

INITIATIVES TO IMPROVE TIMELY REGULATION OF MEDICAL DEVICES

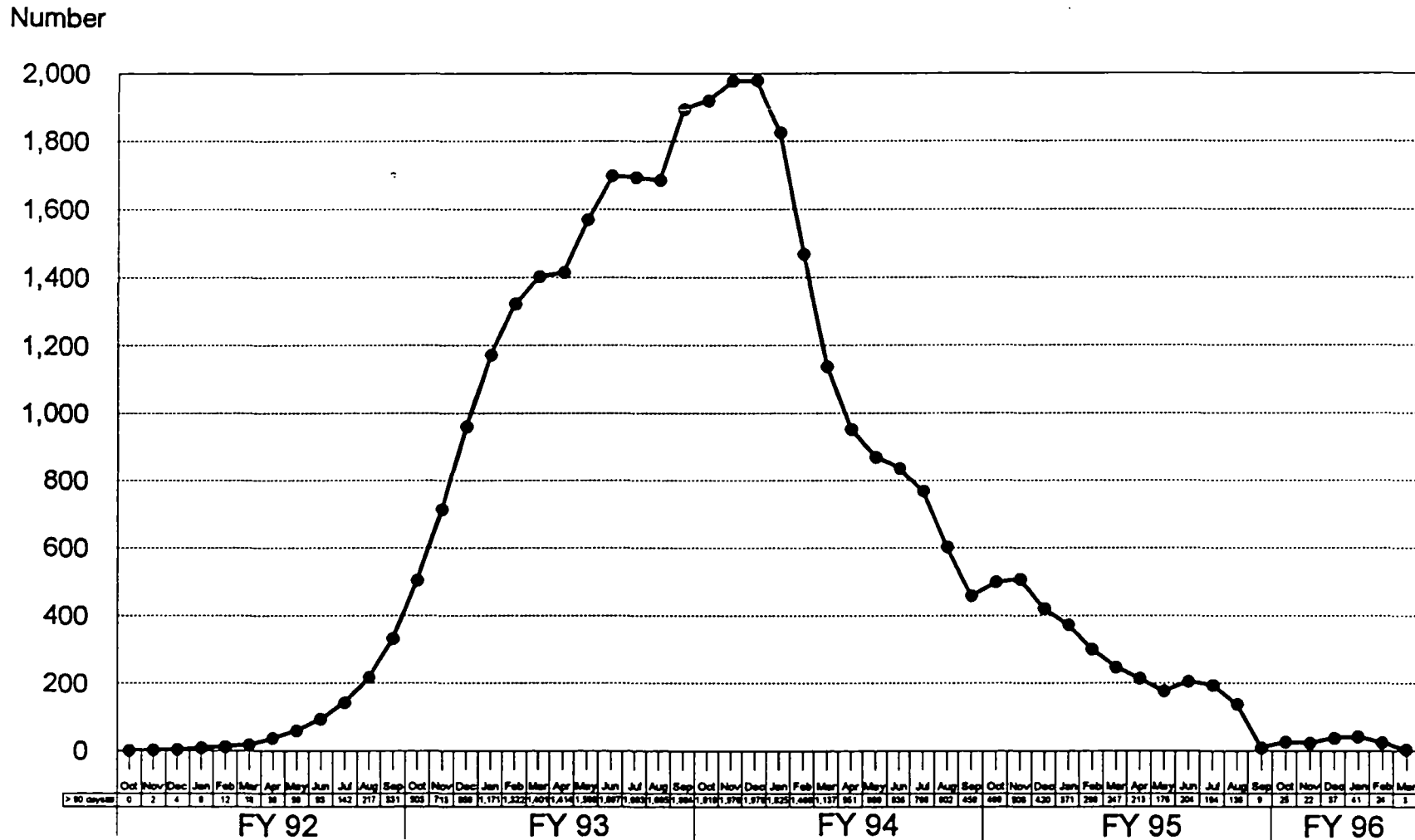
- **Expedited Review Policy**
Products producing a positive health impact on life-threatening or severely disabling conditions and breakthrough products are given priority in the review process. Early and continued interaction with the sponsor is recommended to prevent false starts and/or incomplete data. (Tab A)
- **Refuse to Accept Policy**
Decline to accept 510(k) applications that fail to meet criteria for facial completeness. Allows reviewers to focus their time on applications that are potentially approvable. (Tab B)
- **Triage System**
Product evaluation intensity is based on risk - from review exempt, to lead scientist review, to a full multidisciplinary-team review. (Tab C)
- **Objective Criteria for Device Modifications**
To help a firm determine when a 510(k) is necessary when making a product design, use, or manufacturing change to a device. (Tab D)
- **510(k) Backlog Reduction**
On a one-time basis, resources were re-programmed from other parts of the Center to help review applications. In addition, "like" products were clustered for special "team" review.
- **Exempt Low Risk Products**
In two rounds (December 1994 and January 1996) 269 categories of devices that had produced about 600 applications per year were exempted from premarket review. These exemptions bring the total number of exempt device categories to 572. (Tab E)
- **New Review Staff in Office of Device Evaluation**
In Fiscal Year '94 104 new staff (93 of which were scientific/medical positions) became available through a base increase in appropriations. This has been eroded by the increased cost of maintaining current services in FY '95 and FY '96 but remains higher than FY '93.
- **External Review (Third Party) Pilot Program**
This pilot is to be implemented during the second half of FY '96. (Tab F)

- **IDE Initiative**
This initiative has improved the quality of clinical investigations with most clinical trials approved to begin the investigation within 30 days of IDE receipt. (Tab G)
- **Coordinated Policy with HCFA on Reimbursement for IDE Products**
CDRH has worked with HCFA so that patient charges for most new devices, as they undergo evolutionary design changes needing clinical investigations, are covered under existing reimbursement codes at the level of the approved products they are intended to replace. (Tab H)
- **Formally Project Manage PMAs**
We are training staff in project management and using project management to prospectively plan PMA review process in two review divisions. (Tab I)
- **Productivity Incentive Program**
This program recognizes groups within the organization for superior productivity by increasing the operating dollars for the organization or group by up to \$15,000. (Tab J)

Charts depicting the reduction in the 510(k) backlog and the decrease in total 510(k) review times are attached.

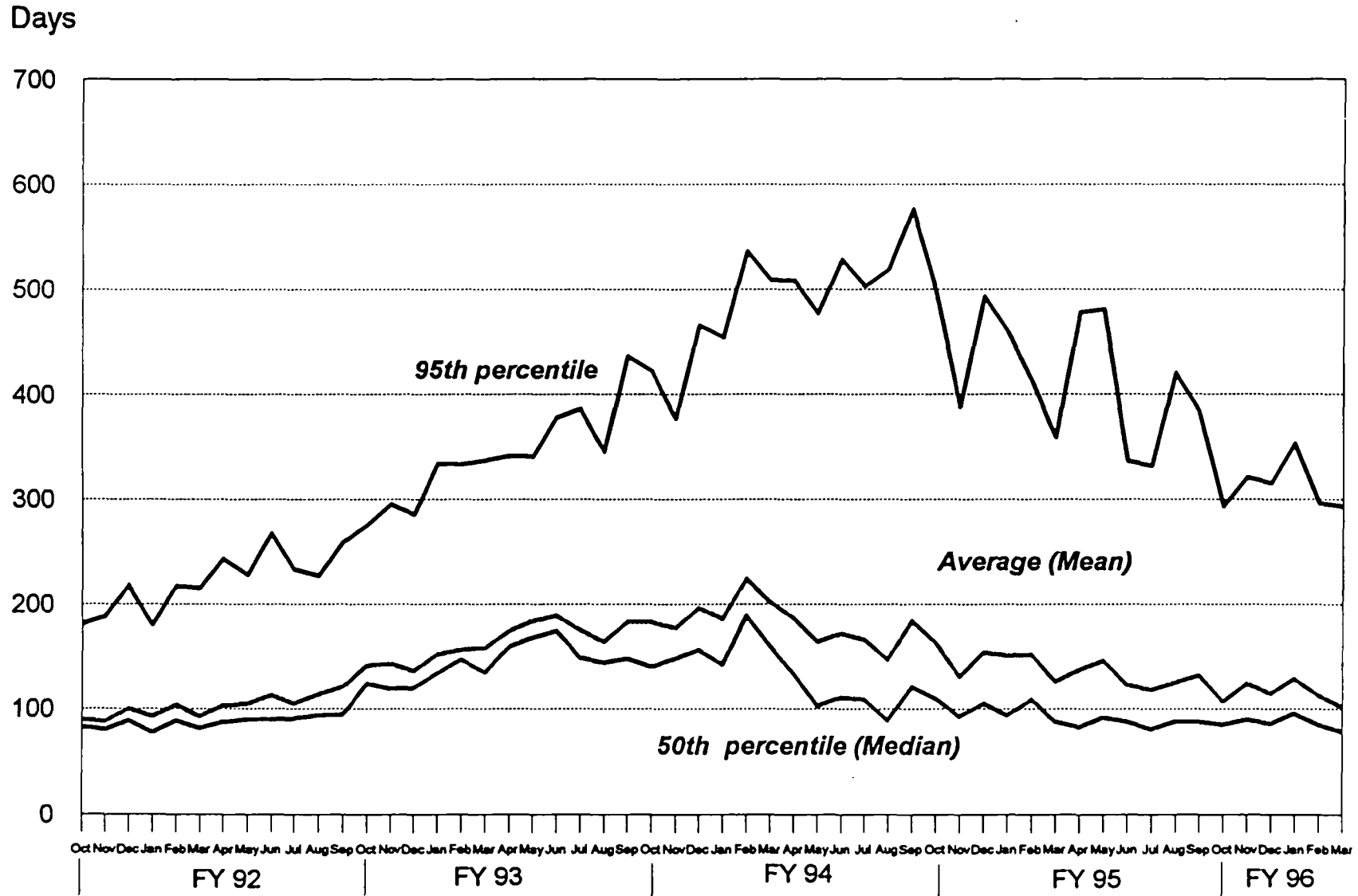
510(k) Backlog

(Under Review More than 90 Days*)



*Reflects the FDA days in current review cycle, not cumulative FDA days
 note: data reflects each month's close of business total, therefore annual totals, based on monthly data above, are not equivalent to ODE's annual report

Total FDA Review Times for 510(k)s



Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

A

Divider Title: _____



Memorandum

Date . MAY 20 1994 General Program Memorandum #G94-2

From Acting Director, Office of Device Evaluation

Subject PMA/510(k) Expedited Review

To ODE Review Staff

Purpose

This document is intended to establish criteria and procedures under which expedited review would apply to Premarket Approval Applications (PMAs) and Premarket Notifications (510(k)s) for medical devices. This memorandum rescinds and replaces 510(k) memorandum #K86-1, "510(k) Expedited Review" and General Program memorandum #G89-2, "IDE/PMA Expedited Review Process."

Introduction

These procedures are based upon the Management Action Plan (MAP) initiative paper entitled "PMA/510(k) Expedited Review Process." This Blue Book Memorandum embodies the guidance procedures flowing from that issue paper and hereby implements the principles in that document as the policy of ODE. This Blue Book Memorandum will be used by ODE reviewers in applying these guidance procedures to the review of incoming PMAs and 510(k)s.

FDA believes it is in the interest of the public health to review PMAs and 510(k)s for certain medical devices in an expedited manner. Expedited review will generally be considered when a device offers a potential for clinically meaningful benefit as compared to the existing alternatives (preventative, diagnostic, or therapeutic) or when the new medical device promises to provide a revolutionary advance (not incremental advantage) over currently available alternative modalities.

Granting of expedited review status means that the marketing application would receive priority review before other pending PMAs and 510(k)s, i.e., the application will be placed at the beginning of the appropriate review queue. If multiple applications for the same type medical device offering comparable advantage over existing approved alternatives have been granted expedited review, they will be reviewed with priority according to their respective submission due dates. Once one of the applications is approved, those of the same type still pending will generally lose their expedited review status as regards review resources but retain their place in the review queue.

Except as specifically noted, documents under expedited review status would be subject to all other controls and requirements applicable to comparable documents in the standard review process. In this effort, it is imperative that valid scientific evidence, as required by Title 21 of

the Code of Federal Regulations, be used to support an application subject to expedited review. This evidence will generally be obtained from well designed, monitored, and controlled clinical trials, when appropriate, so that the true merit of the medical device may be evaluated as promptly and efficiently as possible.

Criteria

Expedited review will be considered for a device intended for or meeting at least one of the following criteria:

1. Life-threatening or irreversibly debilitating conditions with no alternative modality. The condition or potential condition/disease is serious or life-threatening or presents a risk of serious morbidity and no alternative legally marketed diagnostic/therapeutic modality exists.

NOTE: Applications in this category granted expedited review status will not only be placed at the beginning of the review queue but will also undergo accelerated review as review staff are available to be assigned.

2. Life-threatening or irreversibly debilitating conditions with approved alternatives extant, but where new device provides for clinically important earlier diagnosis or significant advances in safety and/or effectiveness over existing alternatives.
3. A revolutionary (breakthrough) device. The medical device represents a clear clinically meaningful advantage over existing technology defined as having major (not incremental) increased effectiveness or reduced risk compared to existing technology. Devices which meet this criteria must have been evaluated utilizing well defined, clinically meaningful outcome measures or acceptable surrogates for such measures.
4. A specific public health benefit. The availability of the device is otherwise in the best interest of the public health. For example, a device designed or modified to address an unanticipated serious failure occurring in a critical component of an approved device for which there are no alternatives, or for which alternative treatment would entail substantial risk of morbidity for the patient.

Procedures

1. Identification of Applications for Expedited Review. Each ODE reviewing Division will identify those applications which merit expedited review, either during the IDE stage, through pre-submission meetings with the applicant or through a preliminary evaluation of the submitted application. This evaluation will take into consideration the criteria set forth above (nature of the medical device, the target population, the alternative preventative, diagnostic or therapeutic modalities and the potential benefit of the device to the public health).

General Program Memorandum #094-2 - Page 3

Sponsors are encouraged to identify early in their correspondence with the Center devices which they feel merit expedited review by the criteria listed above.

2. Determination of Expedited Review. The ODE Division Director will authorize the decision to expedite review within the following timeframes:

510(k)s - The decision to expedite should be made within 30 days from the receipt date of the application.

PMAs - The evaluation for expedited review will be part of the 45 day filing review.

3. Documentation and Processing. After this determination has been made, the Division will prepare a written memo to the administrative record which highlights, using the criteria outlined above, the reasons why the marketing application has received expedited review status. A copy of this memo should be provided to the Director, ODE and the 510(k) or PMA Section of the Program Operations Staff. The Division will prepare and issue a letter, based upon the current boilerplate letter provided by the POS Staff, conveying to the applicant the expedited review status. The notification conveying expedited review status may be incorporated in filing letters. A copy of the letter must be forwarded to the POS office for inclusion in the official administrative file and for updating databases. A boilerplate will also be issued to the applicant if the 510(k) or PMA is later removed from expedited review status.

4. Resource Management. It will be the responsibility of the Director of the reviewing Division to ensure that the application is reviewed in the most efficient manner, tracked as an expedited review, and completed within the statutory time frames. It is recognized that implementation of this policy will impact on all of the review work of the Division. Additional resources may be necessary for review of the marketing applications granted expedited review. All of the following resource issues should be considered to accommodate the expedited review process:

- a) a shift in the workload within the affected reviewing Division may be necessary;
- b) scientists from other Divisions or from outside of ODE may be called upon to provide support to those areas in ODE where the standard review queue would otherwise be affected by the needed redistributions of the workload; and,
- c) review of the other non-expedited applications in that reviewing Division may be delayed.

5. Monitoring. The Office of the Director, ODE, will periodically review, approximately every 90 days, decisions to expedite review to provide feedback to the Division Directors regarding consistency of decision making within and among Divisions.

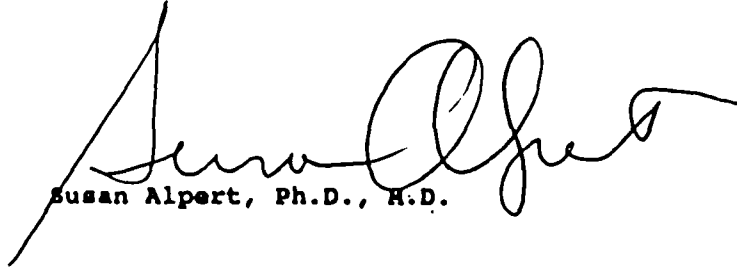
In a separate memo to the Director, ODE, for each application that will receive expedited review, the Division should:

- a) discuss the level of concerted effort the application will require, i.e., a list of the types of reviewers necessary (medical officers, biologists, engineers, etc.) and the level of participation these reviewers will have in the review of the application;
 - b) designate who will be the lead reviewer; and,
 - c) identify the displaced workload, e.g., briefly describe the lead reviewer(s) current workload and the applications that will have to be redistributed.
6. Public Disclosure. The fact that an application has been reviewed under these expedited procedures will be first disclosed to the public only at the time of PMA approval or 510(k) clearance.

A publicly disclosable paragraph should be provided to appropriate media outlets and FDA information sources (OST computer bulletin board, DSHA, etc.) so that interested outside parties may determine what types of applications have been granted expedited review.

Effective Date.

This policy is effective immediately.


Susan Alpert, Ph.D., M.D.

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

B

Divider Title: _____



Memorandum

Date

MAY 20 1994

510(k) Memorandum #K94-1

From

Acting Director, Office of Device Evaluation (HFZ-400)

Subject

510(k) Refuse to Accept Procedures

To

ODE Review Staff

Purpose

The purpose of this memorandum is to establish procedures under which a 510(k) that does not meet a minimum threshold of acceptability will not be accepted for substantive review and clearance.

Background

The Office of Device Evaluation (ODE) receives approximately 6500 Premarket Notification (510(k)) submissions every year. Many of these submissions are incomplete or grossly inadequate, as they fail to contain the components necessary to allow substantive review of the submission. As a means to employ ODE resources more effectively, these procedures are being implemented to ensure that 510(k)s meet a minimum threshold of acceptability; otherwise, ODE will refuse to accept the submissions for substantive review. These procedures will benefit both FDA and submitters.

A primary goal in establishing these "Refuse to Accept Procedures" for 510(k) submissions is to improve the use of our review resources by ensuring that they are focused on the review of reasonably complete and well-supported submissions. It is critical to distinguish between the completeness of the regulatory submission and the quality of the data provided and any studies conducted in support of the submission. These procedures are not intended to mean that ODE should only be expending resources in the review of submissions for devices that, on their face, may be substantially equivalent to a legally marketed predicate device. However, after the initial 510(k) review, the Center will often find that additional data or information is necessary before the reviewer can determine whether the device is substantially equivalent. A decision to refuse to accept a 510(k) will be based on omission of clearly necessary information. By establishing these procedures, with criteria that are clear, consistent, and available to submitters, they will know what is expected of them for the particular submission. Submitters will be likely to comply with the established criteria to speed the time to substantive review and regulatory decision.

These procedures will benefit both FDA and submitters. These procedures are based upon the Management Action Plan (MAP) initiative issue paper entitled "Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy." This Blue Book Memorandum embodies the guidance procedures flowing from that issue paper and hereby replaces that document as the policy of ODE. Attached to the MAP issue paper was a document entitled "510(k) Refuse to Accept Criteria" and an accompanying checklist. As described below, criteria and the checklist will be used by ODE reviewers in applying these guidance procedures to the review of incoming 510(k)s.

Divisions may supplement the general checklist based on available guidance documents appropriate to their specific device areas. Division guidance documents should be promulgated wherever needs are identified. Guidances should provide specific details about what is expected and acceptable for all components of the submissions. Each product specific guidance should include a checklist to be used by a) the submitter in preparing the submission and b) reviewers during the initial evaluation to consider accepting the submission for full review. Checklists should also be prepared for existing guidelines. This will save time and provide consistency across submissions. Also, emphasis should be placed on improved communication with industry.

The document, "510(k) Refuse to Accept Criteria" and any device specific guidance documents and checklists developed by the divisions are being made available to manufacturers and other members of the public by the Center's Division of Small Manufacturers Assistance.

Procedures

This guidance memorandum will be implemented by the review divisions within the Office of Device Evaluation utilizing the following procedures. The specified timeframes are goals that will be met to the extent permitted by available resources.

1. Processing

- a. The ODE Document Mail Center (DMC) will log in, jacket, and distribute the 510(k) to the appropriate review division with the 510(k) Refuse to Accept Checklist and documentation forms within 5 days of receipt in the DMC or as quickly as available resources allow.
- b. A designated reviewer (Branch Chief, Reviewer, CSO, CST) using the 510(k) Refuse to Accept Criteria and checklist, and other appropriate device specific checklists, will determine whether the 510(k) is sufficiently complete to allow substantive review. The division should consult with the Program Operations Staff (POS) on any decision that is particularly difficult or controversial.

- c. Refuse to Accept recommendation(s) will be forwarded to the appropriate supervisor for concurrence within 21 days of DMC's receipt.
- d. If the submission is found to be sufficiently complete to allow substantive review, the 510(k) will be placed into the queue for substantive review.
- e. If the submission is found to be insufficiently complete to allow substantive review, a Refuse to Accept letter will be prepared, in coordination with the POS Staff, for the Division Director's signature. The Refuse to Accept letter, detailing the omissions or inadequacies that led to the decision not to accept the submission will issue within 30 days of receipt of the 510(k). The letter will clearly specify which portion of the submission must be provided if the submitter wishes to pursue clearance for marketing. Copies of pertinent guidance documents will be enclosed with the Refuse to Accept letter.

2. Industry Inquires

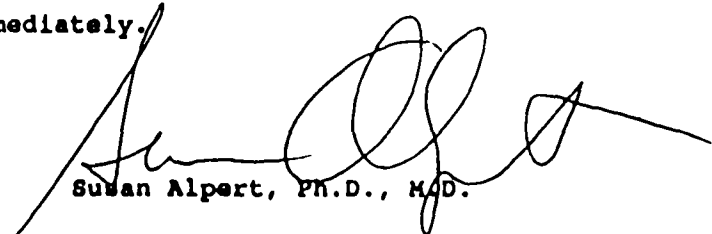
In the event that the submitter has questions regarding the Refuse to Accept letter, the submitter may contact the appropriate Division Director, via letter, telephone, or telefax, regarding the decision.

3. Monitoring

The implementation of the 510(k) Refuse to Accept Procedures will be reviewed by the Office of the Director, ODE, at regular intervals, approximately every 90 days, to determine the number of incomplete and/or inadequate submissions not accepted, the consistency with which the criteria are applied among and within divisions, further necessary refinements to the process, and the overall impact on the 510(k) program.

Effective Date

This memorandum is effective immediately.



Susan Alpert, Ph.D., M.D.

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

C

Divider Title: _____



Memorandum

Date . MAY 20 1994 General Program #G94-1

From Acting Director, Office of Device Evaluation (HFZ-400)

Subject PMA/510(k) Triage Review Procedures

To ODE Review Staff

Purpose

To establish a three tier system using risk assessment to more effectively manage the review workload and for allocating review resources.

Background

The Office of Device Evaluation (ODE) reviews approximately 11,000 regulatory submissions per year. This figure represents the sum of all premarket notifications (510(k)s), premarket approval applications (PMAs), and Investigational Device Exemptions (IDEs), including their supplements.

The devices that are the subject of these submissions range from the simplest Class I devices such as dental chairs and accessories to the most sophisticated Class III devices such as Excimer Lasers used in ophthalmology for refractive surgery. Furthermore, individual submissions within a submission type vary in review difficulty depending upon the scientific issues presented and the quality of the particular document.

It is important to ensure that proper time, attention, and scientific expertise is given to all PMA, 510(k), and IDE applications. Because devices vary in their complexity and risk, the level of effort in evaluation should be appropriate for each type of device, so as to maximize utilization of CDRH resources in the protection of the public health. To this end, we must assess incoming submissions to ensure that sufficient resources are dedicated to the review of high risk Class III devices and that resources are conserved in the review of low risk Class I devices.

Given the finite resources that the Center has available and its responsibility to make sound scientific/regulatory decisions in a timely manner, it is critical that the Center have procedures in place to ensure the proper allocation of resources in the review process to optimize the overall protection that can be provided for public health.

In addition to these triage review procedures, collateral mechanisms are being adopted to identify incomplete or grossly inadequate submissions quickly upon receipt in the agency. The mechanisms for accomplishing this are being addressed separately under Blue Book Memoranda #K94-1, "510(k) Refuse to Accept Procedures", P94-1, "PMA Refuse to File Procedures", and #D94-1, "IDE Refuse to Accept Procedures." If submissions that do not merit

scientific review are identified early in the process, Center resources will be conserved. In addition, Blue Book Memorandum #094-2, "Expedited Review Procedures", which provides for the placement of applications with potentially significant public health benefit at the front of the review queue, will work in conjunction with the refuse to file/accept Blue Book memos and priority setting/resource allocation to further focus utilization of review resources.

The following triage review procedures are based upon the Management Action Plan (MAP) initiative paper entitled "Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources." This Blue Book Memorandum embodies guidance procedures flowing from that "issue" paper and hereby replaces that document as the policy of ODE. This Blue Book Memorandum will be used by ODE reviewers in applying these guidance procedures to the review of incoming 510(k)s and PMAs.

The Triage Review Procedures

1. Each device initially will be assigned to one of the following three tiers based upon the inherent risk of the device.

Tier III - Intensive scientific and labeling review, using a team review approach, for all first and second of a kind devices utilizing new technology or having new intended use(s), as well as other PMAs and 510(k)s determined by their inherent risk to require an intensive review. Advisory panel input is highly recommended for this tier of devices.

Tier II - Routine scientific and labeling review for the majority of 510(k)s and select PMAs.

Tier I - Essentially a focused labeling review for intended use/indications for use.

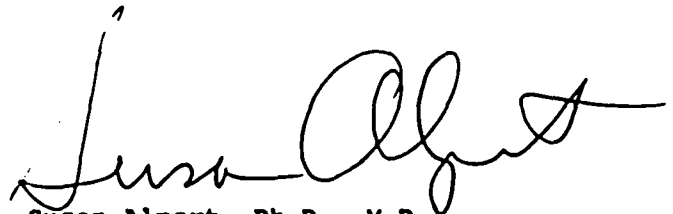
In order to be effective, the system must be flexible to permit the reassignment of applications among the tiers based upon inherent risk, but not so flexible as to allow higher tier reassignments without just cause.

2. ODE staff resources will be reallocated to maximize utilization of existing personnel in the review of devices with major public health impact i.e., temporary reassignment of reviewers and branch chiefs to the busiest, most demanding, public health areas. These temporary reassignments will be advertised so that those responding to the need are aware of its import to the Center and commended for their commitment to the good of the organization.
3. Resources from other areas within CDRH will be identified and utilized to assist in the implementation and achievement of the triage system.

4. The "four of a kind" provision of SMDA will be implemented. This will allow FDA to use the data from the first four PMAs of a particular device to support reclassification or other regulatory reforms.
5. The criteria used to exempt low risk devices from 510(k) regulation will be periodically reviewed and, if necessary, revised.
6. A self-certification process will be developed under which a manufacturer of a low-risk device may certify, using a model statement issued by and acceptable to FDA, that the device conforms with applicable voluntary standards that have been determined by FDA to address most, if not all, safety and effectiveness issues necessary for a determination of substantial equivalence.

Effective Date

This policy is effective immediately.



Susan Alpert, Ph.D., M.D.

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

D

Divider Title: _____

[Docket No. 950-0283]

Deciding When To Submit a 510(k) for a Change to an Existing Device; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an August 1, 1995, draft guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." The draft guidance includes a flowchart model that can be used by manufacturers in their decisionmaking to analyze whether certain changes in a device could significantly affect the safety or effectiveness of the device and, therefore, require submission of a new 510(k). The draft guidance is intended to provide direction to manufacturers, specification developers, and distributors of devices who intend to modify their device and are in the process of deciding whether the modification requires a new premarket notification submission (510(k)).

DATES: Written comments by December 15, 1995.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-8597 (outside MD 1-800-638-2041). Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301-443-8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies of a facsimile of the draft guidance, are available from the Division of Small Manufacturers

Assistance (DSMA) Facts on Demand, Center for Devices and Radiological Health (CDRH), 1-800-899-0381. Copies of the draft guidance may also be obtained from the electronic docket administered by DSMA and are available to anyone with a video terminal or personal computer (1-800-252-1366).

FOR FURTHER INFORMATION CONTACT: Harvey Rudolph, Center for Devices and Radiological Health (HFZ-100), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-2444.

SUPPLEMENTARY INFORMATION:

I. Background

On April 8, 1994, FDA circulated for comment the first draft guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." The draft guidance was intended to provide direction to manufacturers on deciding when to submit a new 510(k) for changes to an existing device. The April 8, 1994, draft guidance was the subject of a May 12, 1994, FDA teleconference. The April 8, 1994, draft guidance was also the subject of discussion at several trade and industry association meetings.

FDA received over 60 comments regarding the April 8, 1994, draft guidance. Based on the comments received, FDA developed an August 1, 1995, second draft guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." FDA is now announcing the availability of the August 1, 1995, draft guidance to elicit further public comment.

II. When to Submit a 510(k) for a Change to an Existing Device

Whenever a manufacturer of a legally marketed device decides to change the device's design or labeling, it is faced with a decision on whether to submit a 510(k). Section 807.81(a)(3) (21 CFR 807.81(a)(3)) states that a premarket notification is required for changes to a currently marketed device that "could significantly affect the safety or effectiveness of the device." FDA staff have tried to define this phrase with greater accuracy, as well as the criteria contained in 21 CFR 807.81(a)(3)(i) and (ii) which are expressed in general terms using adjectives such as "major" and "significant," because they can sometimes lead to subjective interpretation.

FDA's previous attempts to develop guidance in this area have not been entirely successful, and manufacturers have frequently expressed the need for more definitive guidance. FDA has now

developed such guidance and is making it available as a draft for public comment.

III. The Draft Guidance

The draft guidance has been developed to provide aid to manufacturers, specification developers, and distributors of class I, class II, or preamendment (devices in commercial distribution before May 28, 1976) class III devices for which premarket approval has not yet been required under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)) who intend to modify their device and are in the process of deciding whether the modification meets the regulatory threshold for submitting a new 510(k). Whenever possible, the draft guidance attempts to incorporate existing guidance and policy regarding when a 510(k) is necessary for modifications to a currently legally-marketed device.

The draft guidance is not intended to supplant existing definitive guidance for modifications to specific devices, i.e., for daily wear contact lenses. Moreover, the draft guidance is not intended to apply to device kits, nor is it intended to apply to combination products, such as drug/device or biologic/device combinations. The draft guidance is also not intended to address the need for submitting a 510(k) by refurbishers or remanufacturers of devices. FDA intends to develop additional guidance specific to these situations.

The types of modifications addressed in the draft guidance include labeling changes, technology or performance specifications changes, and materials changes. The basis for comparison of any changed device is the device described by a cleared 510(k) or a legally marketed pre-1976 device. That is, manufacturers may make a number of changes without having to submit a 510(k), but each time they make a change, the device they should compare it to is their most recently cleared device or their pre-1976 device, not the current legally marketed device. In effect, manufacturers need to submit a new 510(k) only when the sum of the incremental changes, taken together as though they were in fact one change, exceeds the § 807.81(a)(3) threshold, "could significantly affect the safety or effectiveness of the device."

According to the draft guidance, because many simultaneous changes may be considered in the evolution of device design, each type of change should be assessed separately and, when any one change leads the manufacturer to decide to submit a 510(k), a 510(k) incorporating all

the current changes and comparing the new device to the originally cleared device, or one marketed prior to May 28, 1976, should be submitted. The new 510(k), once cleared, would form the basis of comparison for the next sequence of changes.

The draft guidance consists of a flowchart model to help manufacturers through the logic scheme necessary to arrive at a decision on when to submit a 510(k) for a change to an existing device. The flowchart includes the following three logical breakouts of changes that might be made to a device: Labeling changes, technology or performance specifications changes, and materials changes. To use the model, the questions posed in the flowchart should be answered until the 510(k) holder is directed to consider submitting a 510(k), document the decisionmaking, or notify the agency of the change being effected. The last option occurs for the addition of a contraindication and the necessary documentation would constitute an administrative addition to the 510(k) currently on file.

When contemplating changes to a device, manufacturers should use the flowchart for each individual type of proposed change, e.g., performance specification change, material change, etc. If any one of the changes results in a manufacturer's decision to submit a 510(k), then the 510(k) should be submitted and should incorporate all of the intended changes, as well as a comparison to the originally cleared device described by the 510(k) currently on file with FDA. If a manufacturer's consideration of all proposed changes results in a decision merely to document the decisionmaking, it should document the application of the model along with the necessary records of the validation of changes to the device. In those circumstances where the proposed change is not addressed in the flowchart or in a device-specific guidance document, manufacturers are encouraged to contact the Office of Device Evaluation in CDRH to find out whether other, specific guidance exists or if additional help is available.

IV. Significance of a Guidance

Guidances have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements, but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, the draft guidance is not being issued under the authority of current § 10.90(b), and it does not create or confer any rights, privileges, or benefits for or on any

person, nor does it operate to bind FDA or device manufacturers in any way.

V. Requests for Comments

Interested persons may, on or before December 15, 1995, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether to amend the current draft guidance document.

Dated: October 2, 1995.

Joseph A. Levitt,

Deputy Director for Regulations policy, Center for Devices and Radiological Health.

[FR Doc. 95-25502 Filed 10-13-95; 8:45 am]

BILLING CODE 4160-01-F

**Deciding When to Submit a 510(k)
for a Change to an Existing Device**

Draft #2

August 1, 1995

Draft...August 1, 1995

Preface

On April 8, 1994, FDA circulated for comment the first draft of a document intended to provide guidance to manufacturers on deciding when to submit a new 510(k) for changes to an existing device. That draft was the subject of an FDA/FDLI teleconference on May 12, 1994, and also was the subject of discussion at several trade and industry association meetings. The invitation to comment on the draft guidance elicited over 60 distinct comment letters.

Six of the letters FDA received were from organizations representing multiple manufacturers, while the remainder were from individual manufacturers, consultants and other interested parties. Almost all of these letters contained detailed and thoughtful comments on the guidance and its role in a manufacturer's 510(k) decision making. No attempt will be made here to detail the hundreds of specific comments and changes that were suggested and how they have been incorporated in the second draft of the guidance document, which follows. Nevertheless, FDA staff have attempted to include all pertinent suggestions in this draft of the guidance, and individual submitters of comments should easily recognize where their specific suggestions have lead to revisions.

The comment letters, however, reflected several general themes and concerns regarding the philosophy of 510(k) decision making (particularly for changes to existing products) as well as the respective roles of the manufacturer and FDA in this process. These themes and concerns warrant a discussion since they are a large part of the underpinning of this new draft of the guidance document.

Several writers believed that the April 8 draft ignored the language of the current regulations on premarket notification, Section 807.81(a)(3), where it is stated that manufacturers must submit a premarket notification whenever their product is "about to be significantly changed or modified in design, components, method of manufacture, or intended use." The text of this part of the regulations is provided on the first page of this document and was also provided on the first page of the April 8 draft. The previous draft did not ignore the regulations, but rather, it was an attempt to expand on the phrases "could significantly affect," "major change," "significant change," etc. The April 8 draft as a whole was intended to better define these terms, at least from the FDA reviewer's point of view. Thus, the document did not ignore the regulations, but tried to demonstrate how compliance with the regulation could be achieved. The current draft tries to correct those areas where the April 8 draft fell short of this goal and should provide a reasonable basis for a manufacturer's decision making.

Draft...August 1, 1995

Some of the authors believed that the decision-making process had been inappropriately shifted from the manufacturer to FDA. Although this was not the intent of the April 8 draft, some of the statements can be interpreted in this way, especially when taken out of context. FDA still believes that it is important to define as clearly and carefully as possible when manufacturers ought to submit a 510(k) for a change to an existing device. In some instances, FDA's advice to manufacturers is clear cut, and when asked whether a 510(k) is necessary, FDA's response will always be "yes" or "no." In other instances, the response will depend on a variety of factors. This document attempts to provide for manufacturers FDA's response, were the manufacturer to ask FDA the question of whether a 510(k) would be appropriate for a particular type of change. It is still the manufacturer's responsibility to make that decision for, indeed, the manufacturer knows more about its product and that product's use than anyone else. The guidance contained in this document is only intended to be FDA's best advice. FDA believes that the changes made to the April 8 draft will demonstrate this fact. FDA notes, however, that confusion exists in some of the comments regarding what is the manufacturer's and what is FDA's decision-making responsibility. Manufacturers have the responsibility for determining when a change to their product is significant enough to merit submission of a premarket notification. (If FDA finds, after the fact, that a change was significant and the manufacturer did not submit a 510(k), FDA retains the right to notify the manufacturer of this fact and to require the submission of the 510(k).) FDA's responsibility is the determination of substantial equivalence, based upon the evidence submitted by the manufacturer in a premarket notification.

Several letters noted that FDA's GMP regulations provide adequate control over most design and process changes. They believe that it is unnecessarily duplicative to submit 510(k)s for most changes and that the 510(k) process and the GMP regulations should perform complementary functions. FDA completely agrees with this philosophy. In the April 8 draft, an attempt was made to make explicit the complementary nature of the 510(k) and GMP regulations. Obviously, that attempt was made clear to some reviewers and not to others, since some of the comments complimented FDA for trying to rely more on GMP than upon premarket notification. This difference in viewpoint may derive from individual biases regarding the limits of design validation for changes. In this draft guidance, the reliance on design validation of changes under GMP is much more explicit, and, in many instances, the results of design validation activities are identified as indicators of when a change is significant enough to merit a premarket notification.

The comments also discussed what should be included in a 510(k), once the decision to submit a new 510(k) has been made. The statement in the April 8 draft that "when any one change requires the submission of a 510(k), then a 510(k) incorporating all the changes, including any prior incremental changes, must be submitted...the new 510(k) should incorporate the old 510(k) and identify and

Draft...August 1, 1995

discuss all the changes made to date," caused some confusion. In some instances, the statement was interpreted to mean a description would be necessary of each and every engineering change made since the most recent 510(k) submission. This was definitely not intended. The 510(k) for the changed product, however, must discuss all of the differences between the old and the new product, in order for a determination of substantial equivalence to be possible. In most instances, this is currently accomplished by the provision of a table describing major differences in performance specifications and indications for use or other labeling issues. Further, it is not necessary to "physically" include the old 510(k) with the new 510(k), but the original 510(k) should always be identified and referenced.

The question of consultation with FDA was discussed at great length. In order for this or any other guidance to work well, it is important that feedback be provided to FDA of where it works well and where it does not work so well. The April 8 draft was intended to stimulate manufacturers to contact FDA with those decisions where the guidance was not useful (called decisions in the gray area) in order to refine the guidance at some future date. It was not intended that manufacturers refrain from their decision-making pending an FDA determination; the choice of words in the April 8 draft was unfortunate in this regard. Manufacturers certainly make their own decisions on whether to submit a premarket notification, however, in those instances where this guidance does not prove useful, FDA would like to be notified so that these issues can be clarified in future revisions.

The model that was discussed in the April 8, 1994, document was described as a matrix model. In reality, the model combined the use of a flowchart with a matrix-like array of advice for each type of device and device change to guide decision making. The advice contained in the matrix was whether to submit a 510(k) or merely to document the decision-making under the current Good Manufacturing Practices regulation (21 CFR 820) for changes in device design, components, packaging or labeling.

The current model no longer contains the matrix. This was done for two reasons. First, the changes made as a result of the comments diminished the need to rely on a matrix-like illustration of the advice being given. A more generic approach was taken in the model, and there was less need to differentiate among specific device types. In the few instances where the type of device would have an impact on the guidance, this was taken into account in the flow diagram. Thus, the flow diagram in this model is more complex than the April 8 version, but the matrix has been eliminated.

Second, the use of a matrix appeared to confuse many more people than it helped. If the purpose of a guidance document is to clarify regulatory responsibilities, elimination of any source of confusion is beneficial, thus the demise of the matrix.

Draft...August 1, 1995

Many of the writers believed that this guidance is of sufficient importance that it is necessary to provide notice and comment through the Federal Register. FDA does not believe that this document constitutes either a substantive or procedural rule, and, consequently, notice and comment through the Federal Register is not necessary. FDA is cognizant, however, of the potential widespread use of this document, and, therefore, a Notice of Availability has been prepared for publication in the Federal Register to announce the second draft of this guidance for further public comment.

TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE</u>
Preface	1
Introduction	1
The 510(k) Process and Good Manufacturing Practices	2
Scope of the Proposed Guidance	3
Assumptions/Axioms	4
Proposed Model	5
Labeling Changes	7
Technology or Performance Changes	10
Materials Changes	13
Materials Changes in In Vitro Diagnostic Products	16
Flowchart Definitions	18
Figures	23
Appendix A	28

Introduction

Almost from the enactment of the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act in 1976, FDA staff have attempted to define with greater accuracy when a change in a medical device would trigger a need for a manufacturer to submit a premarket notification (510(k)) to the Agency. The regulatory criteria contained in §807.81(a)(3) state that a premarket notification must be submitted when:

(3) The device...is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

The key issue here is that the phrase "could significantly affect the safety or effectiveness of the device" and the use of the adjectives "major" and "significant" sometimes lead to subjective interpretations. Because of this, manufacturers have frequently expressed the need for more specific guidance in applying the regulatory standard in their decision making.

Previous internal attempts to develop such guidance on interpreting the regulation have focused generally on defining broad issues or principles that should be used in deciding when to submit a 510(k). These attempts have been only partially successful in clarifying the situation. The primary reason for partial success is that the variety of device types currently marketed, as well as the myriad changes that occur as technology evolves, are so diverse that one or two unifying principles cannot possibly account for all decision-making opportunities.

To be certain that a decision on when to submit a 510(k) is correct, one would probably need to enumerate all device types and all potential types of changes and then match each combination of device and change with a decision. Given that there are thousands of individual device types and possibly tens or hundreds of enumerable changes, this would be an extremely difficult task. Furthermore, the resultant guidance would fill volumes, would probably be difficult to use and would be unlikely to keep pace with an ever-changing technology.

Draft...August 1, 1995

Between the two extremes of broad principles and detailed enumeration is the area where models can be developed to assist in the decision making. If created and used properly, such a model could provide guidance leading toward a rational answer as to whether a 510(k) is necessary in the large majority of circumstances. This document proposes a flowchart model that can be used by manufacturers in their decision making to analyze how changes in devices may affect safety or effectiveness. In the model, we attempt to address changes to devices at a level detailed enough so that application of the broad principles espoused by the agency would assure a very high percentage of "correct" decisions. The goal of the model is to provide guidance in answering a manufacturer's (or other 510(k) holder's) questions on whether a 510(k) is necessary for a particular type of change and to minimize the number of situations where the answer would be uncertain.

The 510(k) Process and Good Manufacturing Practices

Any guidance on 510(k)s for changes to a marketed device must consider the role of the Good Manufacturing Practices (GMP) regulation in changes in device design. For some types of changes to a device, the Agency continues to find that a 510(k) is not necessary and that reliance on existing GMP requirements may reasonably assure safety and effectiveness of the changed device.

It is important to note that the current GMP regulation does not directly address the original design of a device. In fact, it was the recognition of the need for this type of control for many types of devices that led to the inclusion of pre-production design controls in the Safe Medical Devices Act of 1990.¹ The recently proposed new GMP regulation will implement the new authority and directly address design controls for new devices.

The current GMP regulation, however, is not silent on device design. It requires manufacturers to document in the device master record (§820.181) any changes (and internal approval to changes) to device design and any associated testing (§820.100). It also requires process validation to assure that products meeting the designed quality characteristics will consistently be produced (§820.5 and §820.100). Finally, manufacturers must have a formal approval procedure for any change in the manufacturing process of a device (including those dictated by design changes) (§820.100(b)(3)).

The net effect of the GMP regulation is to require that, when manufacturers make a change in the design of a device, they must have a process in place to demonstrate that the manufactured product meets the change in design specifications (or the original specifications, if no change was intended). They must keep records, and these records must be made available to an FDA inspector. Thus, although the current GMP regulation does not address the initial design of a device (the proposed

Draft...August 1, 1995

revision to the GMP regulation does address the need for design controls for many products), it does impose certain requirements when changes to a device are implemented. For many types of changes to a device, it may be found that a 510(k) is not necessary, and the Agency may reasonably rely on the existing GMP requirements to assure safety and effectiveness of the changed device. This reliance is enhanced when manufacturers document their decision making based on their testing results or other design validation criteria.

Scope of the Proposed Guidance

The guidance outlined in this document has been developed to aid manufacturers, specification developers or distributors of class I, class II or pre-enactment class III devices (for which premarket approval has not yet been required under section 515(b)) who intend to modify their device and are in the process of deciding whether the modification meets the statutory threshold for requiring a new 510(k) submission. This guidance for changes to an existing device is intended to supplement the general guidance on submitting 510(k)s contained in the ODE bluebook memorandum on the premarket notification program.²

The types of modifications addressed in this document include modifications to design as well as modifications to device labeling, such as modified indications for use, claims for safety and effectiveness, etc. Furthermore, this guidance can be applied to those situations when a legally-marketed device is recalled and a change in device design or labeling is indicated and has not been previously evaluated by the Agency.

This guidance is not intended to apply to device kits (as defined by the 510(k) certification policy memo of April 23, 1994)³, nor is it intended to apply to combination products, such as drug/device or biologic/device combinations. Furthermore, this guidance is not intended to address the need for submitting 510(k)s by refurbishers or remanufacturers of devices. FDA intends to develop additional guidance specific to these situations.

This document attempts wherever possible to incorporate existing guidance and policy regarding when 510(k)s are necessary for modifications to a currently legally-marketed device.⁴ In some cases, the existing guidance derives from advice given to only a few manufacturers for a limited number of devices. In such instances, we have attempted to generalize the concepts to apply to a broader range of devices. However, special cases exist where both manufacturers and FDA have worked to establish definitive guidance for modifications to specific devices, e.g., for daily wear contact lenses.⁵ This guidance is not intended to supplant such existing device-specific guidance.

Assumptions/Axioms

In developing this guidance for aiding in the decision on when to submit a 510(k), a number of assumptions had to be made. Some derive from existing 510(k) policy and are widely known, others are necessary for using the logic scheme contained in this guidance. Thus, anyone using this guidance needs to bear in mind the following assumptions:

- Any person required to register under 21 CFR 807.20, who plans to market a device requiring premarket notification, will always have to submit a new 510(k). (Note that private label distributors and repackagers are exempt from submitting a 510(k) if they satisfy the requirements of 21 CFR 807.85(b).)
- The guidance applies to the change intended by the manufacturer and not any unforeseen results of implementing that change (although unforeseen results may impact safety and effectiveness and, thus, may be key in deciding to submit a 510(k)).
- The basis for comparison of any changed device is the device described by a cleared 510(k) (or a legally marketed pre-1976 device). That is, manufacturers may make a number of changes without having to submit a 510(k), but each time they make a change, the device they should compare to is their most recently cleared device (or their pre-1976 device), not the current legally marketed device. Although a single incremental change to a device may not substantially affect safety or effectiveness, the sum of many incremental changes can have a substantial effect on safety or effectiveness. Thus, manufacturers can only assure themselves that the last change has not had a significant effect by comparing to the most recently cleared device (or the device marketed prior to May 28, 1976). In effect, manufacturers need to submit a new 510(k) only when the sum of the incremental changes (taken together as though they were in fact one change) exceeds the regulatory threshold, described by the phrase, "could significantly affect the safety or effectiveness," for submitting a new 510(k).
- Because many simultaneous changes may be considered in the evolution of device design, each type of change must be assessed separately, and, when any one change leads a manufacturer to decide to submit a 510(k), then a 510(k) incorporating all the current changes and comparing the new device to the originally cleared device (or one marketed prior to May 28, 1976) must be submitted. Note that this comparison may be done via a

Draft...August 1, 1995

table or other means. The new 510(k), once cleared, would form the basis of comparison for the next sequence of changes.

- Whenever manufacturers change their device, they must comply with the Good Manufacturing Practice regulation.⁶ This regulation requires that specification changes be subject to controls as stringent as those applied to the original design specifications of the device, and that such changes be approved and documented by a designated individual(s), which includes the approval date and the date the change becomes effective (21 CFR 820.100(a)(2)). This means that when a change is made to the device, there is verification through testing that the change does not adversely affect the device's safety or effectiveness. Only then can manufacturers assure an accurate assessment of the change(s) in the device in applying this guidance. They must maintain records of the validation under the current GMP. It is this validation of the changes and the documentation maintained by manufacturers that can support the decision on whether to submit a 510(k).
- To derive maximum benefit from this guidance, manufacturers should have in place a mechanism for evaluating whether a proposed change meets the regulatory threshold for a new 510(k). This mechanism could also document use of this guidance, if applicable, or other decision-making aids or bases for deciding whether a 510(k) is necessary.
- This guidance can not address every type of change to every type of device. No matter how ingeniously this guidance is applied, there will still be decisions in the "gray areas" that manufacturers will have to make. If manufacturers notify the Office of Device Evaluation of these instances, the gray areas can be better defined and understood, and, ultimately, this guidance can be refined to encompass the new areas.
- Manufacturers should understand that, even though they use this guidance and submit a 510(k), a substantial equivalence determination is not assured. Some changes to a device may be sufficiently significant that the changed device would be determined to be not substantially equivalent and a premarket approval application would be required before the device could be marketed.

Proposed Model

The model proposed here uses a flowchart to help manufacturers through the logic scheme necessary to arrive at a decision on when to submit a 510(k) for a change to an existing device. A single

Draft...August 1, 1995

flowchart containing all the logical steps necessary is large and cumbersome and could be quite daunting. Therefore, it is not included in this document. Rather, for ease of use, Figure 1 depicts the three logical breakouts of changes that might be made to a device:

- labeling changes,
- technology or performance specifications changes ,and
- materials changes.

The reader is referred to Figure 2 for labeling changes and to Figure 3 for technology or performance specifications changes. Materials changes are addressed by the flowchart in Figure 4, with the exception of materials changes for in vitro devices (IVDs), which are addressed by the flowchart in Figure 5.

To use the model, one must answer the questions posed in the flow chart until either directed to consider submitting a 510(k), document the decision-making, or notify the Agency of the change being effected. This last option occurs for the addition of a contraindication and the necessary documentation would constitute an administrative addition to the 510(k) currently on file.

When contemplating changes to a device, manufacturers should use the flow chart for each individual type of proposed change, e.g., performance specification change, material change, etc. If any one of the changes results in a manufacturer's decision to submit a 510(k), then the 510(k) should be submitted and should incorporate all of the intended changes, as well as a comparison of the changed device to the originally cleared device described by the 510(k) currently on file with the Agency. If a manufacturer's consideration of all proposed changes results in a decision merely to document the decision-making, it should document the application of the model along with the necessary records of the validation of changes to the device.

For those circumstances where the proposed change is not addressed in the flow chart or in a device-specific guidance document, manufacturers are encouraged to contact the Office of Device Evaluation in CDRH to find out whether other, specific, guidance exists or if additional help is available.

Before using the flowchart, the reader is reminded that specific guidance has been developed for changes to a legally-marketed device that result from a recall. That guidance has been developed separately, but its philosophy is similar to this document in that changes to a product that are intended to bring a product back to its original specifications and that can be validated under GMPs

Draft...August 1, 1995

do not require a 510(k). On the other hand, changes in specifications that raise issues of safety or effectiveness would require a 510(k).

Note that the flowchart entries, "new 510(k)" and "documentation," are written in this way only for conciseness. The reader should interpret "new 510(k)" as **strongly consider submitting a 510(k)** and "documentation" as **document your analysis and file it for future reference**. This is, after all, a guidance document, and it is not intended to be prescriptive. It is intended only to provide the outline of a logic scheme for enhancing the likelihood of good decisions.

Each of the questions listed on the detailed flowcharts (Figures 2-5) are identified by the flowchart letter (A through D) and a sequential number. Those questions on the main spine of the flow charts relate to major questions to be asked and are identified by a letter and an integer, such as **A1, A2**, etc. Subsidiary questions that are asked in response to a "yes" answer are identified by the integer for the question, a decimal point and a sequential integer, e.g., **C2.1** in Figure 3 labels a decision point containing the question "(Is there a) Change in device performance specifications?" which follows the determination made in decision point **C2** that a change in material type is contemplated.

Labeling changes

As noted above, the types of changes are divided into labeling changes, technology or performance specifications changes, and materials changes. All labeling changes are handled with a separate logic scheme that concentrates on changes in indications for use as the threshold for contemplating the submission of a 510(k). Other labeling changes are more frequently recommended for documentation only.

Chart A (Figure 3) describes the logic scheme to be used when contemplating the need for a 510(k) for a labeling change. Changes in device labeling often pose the most difficult questions to be addressed by device manufacturers when deciding whether a new 510(k) submission is necessary. Frequently, a rather subtle change in a device labeling can have a significant impact on the safe and effective use of the device.

A 1 **Is the labeling being revised for clarity, safer use or effectiveness?** Device labeling may be changed for a multitude of reasons. Probably, most labeling changes result from attempts to clarify instructions or to make the device easier, safer or more effective to use. In most instances, such labeling changes would not result in the need to submit a 510(k). For example, the instructions for use of an automated clinical chemistry analyzer may be

modified to clarify how routine batch testing operation may be temporarily interrupted to allow efficient processing of high priority samples. No 510(k) would be necessary in this instance. If the question of a 510(k) submission did arise, however, manufacturers should document the rationale for their decision.

- A 2** Does the change affect the indications for use? Changes in the indications for use section of labeling raise more agency concern than any other aspect of labeling. In fact, changes in this part of the labeling will in most instances require the submission of a 510(k). For all practical purposes, the only substantial change in the indications for use that could occur without the submission of a 510(k) is when the change limits use to within the currently cleared indication. For example, the device was cleared for use with three specific indications and the firm decides to market the device for only two of those indications. Another example would be further limiting the patient population by age or weight. In determining whether a change to the indications for use raises issues of safety and effectiveness, the manufacturer should ask whether the specific uses pose any additional risks or expand the use to a new patient population.

Confusion often results when discussing the distinction between "indications for use" and the "intended use" of the device. The regulatory term, "intended use," refers to objective intent of the persons legally responsible for the labeling of the device. Intent may be determined by written expressions or may be shown by the circumstances surrounding the distribution of the device. The concept of intended use has particular relevance in determining whether a device can be cleared for marketing through the premarket notification (510(k)) process or must be evaluated in a premarket approval application (PMA). Manufacturers should recognize that if a particular labeling change results in a "new" intended use for the device, the Agency will find the device to be not substantially equivalent and require premarket approval.

For the purpose of this guidance, we have elected to avoid referring to "intended use" as a determinant in deciding when to submit a 510(k). We have chosen, rather, to identify the specific changes or modifications that we believe have a major impact on intended use and thus would require the submission of a 510(k) (§807.81(a)(3)). Two common labeling changes that impact intended use and would usually require submission of a 510(k) are:

- (1) reuse of devices previously labeled "single use only;" and
- (2) changes from prescription to over the counter or OTC.

One exception to (2) above is providing home-use instructions for devices that remain prescription and whose movement to use in the home is accepted medical practice in the United States. Many prescription devices are used in the home with increasing frequency and the Agency believes that 510(k)s are not necessary for the labeling changes. The reader is referred, however, to the FDA publication, "Write It Right,"⁷ for techniques to provide clear and understandable home use instructions.

- A 3** **Is it a change in warnings or precautions?** In order to facilitate a continuous upgrading in device labeling, manufacturers should monitor device usage and promptly revise the warnings and precautions section based on use experience. 510(k)s for such changes are generally unnecessary unless new issues of safety or effectiveness have arisen to cause the change in labeling, however, manufacturers should document these changes in their files.
- A 4** **Does the change add a contraindication?** While all changes in the labeled contraindications for device use should be reviewed by the Agency, CDRH recognizes that the addition of a contraindication based on new information is important to public health and should be implemented immediately. Because of this, manufacturers are encouraged to add new contraindications to their labeling and to notify existing users of their device as expeditiously as possible whenever a pressing public health need arises. The new labeling can be submitted to FDA after the fact as an addition to the existing 510(k) (indicating that the change is already effected). Manufacturers may continue to market their product with the modified labeling, unless otherwise notified by FDA. Manufacturers should be thoroughly familiar with what constitutes a true contraindication to do this.
- A 5** **Does the change delete a contraindication?** On the other hand, deletion of a contraindication usually requires the submission of a 510(k) prior to effecting the change. In effect, deletion of a contraindication expands the Indications for use and, thus, would normally require submission of a new 510(k).

FDA believes that, if manufacturers follow this approach to changes in device labeling, the maximum number of necessary 510(k)s (those changes that pose the potential to significantly impact safety and effectiveness) will be submitted while minimizing the submission of unnecessary 510(k)s (those where safety and effectiveness are unlikely to be affected). At the same time, manufacturers should be able to retain the flexibility to update and clarify their labeling to maximize the safe and effective use of their devices.

Technology or Performance Changes

Chart B illustrates the decision making logic scheme for technology or performance specifications changes to a device.

B1 **Is it a control mechanism change?** Almost all changes in the control mechanism for a device raise questions of safety and effectiveness. Therefore, such changes will normally require the submission of a new 510(k). This is also true for changes in operating principle (decision point B2) as well as for changes in energy type (decision point B3). (This last was recognized as a significant change both in the statute⁸ and the implementing regulations.⁹) Changes of these types tend to be more revolutionary than evolutionary.

One obvious example of a control mechanism change that would raise new questions of safety and effectiveness would be the change from analog to digital control of a medical device. While the change to digital control can markedly improve device performance specifications and effectiveness, the integration of a digital control into a previously all analog system is complex and usually undertaken only as part of a major redesign of a product. Thus, it would be rare that a new 510(k) would not be necessary. Most often, such changes in control mechanism represent the introduction of a new product line.

Other changes in control mechanism of a similar nature would also lead to submission of a new 510(k). Examples of such changes would be the change from pneumatic to electronic control of a respiratory care device or a change from manual power to compressed gas power for a mechanical surgical stapler.

B2 **Is it an operating principle change?** Similar to a control mechanism change, a change in operating principle would also normally lead to the submission of a 510(k). A typical example of a new operating principle for a device would be changing the image reconstruction algorithm used in a computed tomography x-ray system from simple back projection to a new, more radiation-efficient method. In this case, testing both at the bench and in the clinic would be necessary to support a finding of substantial equivalence for the new device. Such changes may also be accompanied by significant labeling changes and, sometimes, by a need for operator retraining to assure continued safe and effective operation. Note, however, that some minor changes to the algorithm that can easily be validated by the manufacturer may not require the submission of a 510(k). Such incremental software changes are discussed under decision point B8 below.

B3 **Is it a change in energy type?** Here, too, the submission of a 510(k) will be the likely result of a manufacturer's decision making. For example, changing from AC to battery power is usually part of a redesign to provide a portable device that can be used under different environmental conditions than the original device. Such a change would normally be accompanied by significant labeling changes, including a new or expanded indication for use. Note that this type of change does not include a change from 3V to 9V operation or a change from NiCad to lead acid storage batteries. Such changes would be considered changes in performance specifications or technical specifications and are discussed at decision point B5 below.

B4 **Is it a change in environmental specifications?** See B8 below.

B5 **Is it a change in performance specifications?** See B8 below.

B6 **Is it a change in ergonomics of the patient/user interface?** See B8 below.

B7 **Is it a change in dimensional specifications?** See B8 below.

B8 **Is it a change in software or firmware?**

The types of changes identified at decision points B4 through B8 have frequently been called design changes or engineering changes. They encompass everything from the routine specification changes necessary to maintain or improve device performance as a result of feedback from users, field or plant personnel, etc., up to and including significant product redesign. The major difficulty lies in sorting out which of these changes is significant enough to trigger the need for a 510(k). The logic scheme that follows is intended to lead a manufacturer through a thought process that will allow routine engineering change orders to occur, while identifying those changes for which a 510(k) would be indicated.

B8.1 **Does the change affect the indications for use?** As with a labeling change, if the indications for use are affected, a 510(k) is probably necessary. An example of this would be changing the length of a surgical scissor from 4 inches to 12 inches so that the device could be used in laparoscopic procedures. The original indication was for open surgical procedures, while the new indication is for closed, endoscopically-controlled, procedures. Note that even though a surgical scissor is exempt from 510(k) by classification rule, one must still evaluate the change to assure that the change does not affect the device's classification.

- B8.2 Are clinical data necessary to establish safety and effectiveness for purposes of substantial equivalence?** Whenever a manufacturer recognizes that clinical data are needed and that bench testing or simulations are not sufficient to establish the substantial equivalence of a new design, it is clear that a 510(k) is necessary.
- B8.3 Are clinical data necessary to show continuing conformance to a recognized standard?** Although the need to collect clinical data for establishing substantial equivalence usually means a 510(k) is necessary, the mere fact that clinical data are collected does not imply the same thing. Frequently, clinical data of some sort may be necessary to demonstrate that device performance continues to conform to a voluntary standard. This frequently occurs for relatively minor changes to *in vitro* diagnostics that are labeled as meeting particular NCCLS standards. Such changes do not normally require a new 510(k).
- B8.4 Do results of design validation raise new issues of safety and effectiveness?** All changes to product design will require some level of design validation to assure that the product continues to perform as intended. The successful application of routine design validation activities will logically result in manufacturers documenting their efforts and proceeding with the design change, i.e., no issues of safety or effectiveness are raised. Occasionally, however, either routine design validation activities produce unexpected results or otherwise prove to be inadequate to validate the design change. In such instances, questions of safety and effectiveness may be associated with the design change, and the manufacturer may need to submit a new 510(k).

For example, a manufacturer sees the need to add a higher kilovoltage position on the control of a conventional diagnostic x-ray system. The results of the design change are predicted based on models, calculations, etc. The new system is used to image a phantom and all results are as predicted. The manufacturer documents the efforts and proceeds to production. On the other hand, a manufacturer of monitoring devices wants to use a more sensitive comparator circuit and makes other design changes to accommodate the more sensitive component. Tests with a simulator produce unexpected results, and additional work is necessary to rationalize what has occurred. The manufacturer should carefully assess what has been done and whether new questions of safety or effectiveness have been uncovered. One key to the answer (but not the only one) is whether a significantly different scheme for design validation was necessary.

- B9** Is there a change in packaging or expiration dating? Generally, changes in device packaging or changes in the expiration date for device use usually do not result in the need for a new 510(k). Such changes are properly within the function of GMPs. This is true whether the manufacturer applies an expiration date because of package integrity considerations or because of finite shelf life of the device. The reader should note however, that changes in packaging wherein two or more separately packaged products are combined as a kit will be addressed in a separate guidance document on kits.¹⁰
- B10** Has there been a change in sterilization? Changes in sterilization have the potential for affecting the safety or effectiveness of the device and, thus, must be carefully assessed.
- B10.1** Has there been a change in performance specification of the device or in the sterility assurance level attained as a result of the change in sterilization? Changes in the method of sterilization have the potential for changing performance characteristics of a device. This is particularly true of materials properties of plastics. When manufacturers make changes in sterilization methods, they must document that important properties of the device do not change as a result. In addition, if the sterility assurance level is changed, manufacturers must assess whether device safety or effectiveness may have been compromised by the new (lower) level. Manufacturers need, in these instances, to assess critically the need for a new 510(k) for their product.

Materials Changes

Firms making changes to the materials from which their device is manufactured first need to consider the other types of changes discussed above and their impact on the decision regarding the need for a new 510(k). For example, a change of a material type, as discussed below, might also engender a change in the labeling of the device, e.g. the removal of a contraindication or the addition of a new warning. These changes should be considered first, before applying the logic scheme described in this section. See Chart C.

- C1** Is the device an in vitro diagnostic product (IVD)? If the device is an IVD, refer to the later section of this Guidance which is specific to materials changes in IVD's (Chart D).
- C2** Is this a change in type of material from which the device is manufactured? Is the generic type of material being changed? There is considerable discussion available regarding what is meant by generic materials types. FDA is developing a Biomaterials Compendium for

Draft...August 1, 1995

implant devices which will give form and structure to this discussion. The goal of this Compendium is to relate the type of device to the materials of manufacture. Appendix A to this Guidance is a draft of the current tables of generic materials from that Compendium. (It is anticipated that the tables from the Biomaterials Compendium will become final by the time this guidance on when to submit a 510(k) becomes final.)

- C2.1 Is there a change in performance specifications?** Frequently, a change in materials is made to purposefully alter the performance specifications of a device. In this case, decision point **B5** should be used (in addition to this one) to help decide whether a 510(k) is necessary. Sometimes, however, changes in materials can inadvertently affect performance of a device. Under GMPs, manufacturers are responsible for assessing this possibility. If performance specifications are inadvertently changed, it is possible that a new 510(k) is necessary. Manufacturers should still use the logic scheme beginning at decision point **B5** to help decide whether a 510(k) is necessary.
- C2.2 Is the device an implant?** Implant devices are those described in the "permanent contact" category of ISO 10993-1.¹¹
- C2.2.1 (Since the device is an implant) Will the material of the affected part of the implant be likely to contact body tissues or fluids?** Changes in materials that contact body tissues or fluids may critically affect the device's safety or effectiveness, either because of potentially new interactions of the device material on the body or because of the body's environmental effects on the new material in the device. Except in very restricted circumstances, manufacturers are likely to opt for submitting a new 510(k) in this instance. Examples of devices for which changes in material type would normally require a new 510(k) are total joints or their components. On the other hand, changes in materials of an implant that are not intended to contact body tissues or fluids are not likely to require a 510(k). Examples of such changes in material type are changes in the interior materials of an implantable electric stimulator (e.g., a single chamber cardiac pacemaker) which are sealed from ingress of body fluids or tissues.
- C2.3 Will the material of the affected part of the device be likely to contact body tissues or fluids in vivo?** Since the decision in box **C2.2** above sorted from consideration the implant devices, the remaining devices, i.e. those for which a "yes" answer is appropriate, include both "limited exposure" and "prolonged exposure" devices, as described in ISO 10993-1: Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. Examples of prolonged

exposure devices which might contact in vivo fluids or tissues are: a parenteral feeding catheter; a wound drain; an infusion catheter; sutures; etc.

C2.3.1 Considering that the material is likely to contact in vivo body tissues or fluids and the requirements of ISO 10993-1, is additional testing required? ISO 10993-1 outlines a rational process by which a manufacturer can determine which types of biological evaluation should be performed on a device prior to its use with patients. Proper consideration of the various aspects of this evaluation should lead the manufacturer to consistent decisions regarding the changes to the material and the necessity of additional testing. If such additional testing is required, a 510(k) is usually necessary.

C3 **Is this a change in the formulation of the material, but not a change in material type?**
These are changes within a single generic material type that can affect the chemistry, metallurgy or other property or stability of the material. These do not include changes in processing aids, catalysts, residual contaminants or manufacturing aids that are not intended to be part of the material. An example of a change in material formulation is a change from one type of polyurethane to another or a change from a AISI Type 316 stainless steel to a AISI type 400 stainless steel. To determine the need for a 510(k) for a change in material formulation, the same logic used for a change in material type should be followed. (See C2.1 above.)

C4 **Is there a change in the vendor of the raw material from which the device is manufactured?** Changes in the suppliers of raw materials to the manufacturers of medical devices are described in both the existing GMP Regulations and 510(k) Regulations. These regulations establish the responsibility of the device manufacturer to purchase those materials against a materials specification. Such a specification requires performance characteristics of the raw materials related to the desired performance of the finished device. The controlling aspect of the logic scheme for this change is the existence of such a material specification.

C4.1 **Is the new material being supplied to a specification?** If the material is being supplied to a specification, a 510(k) is probably not required. For example, a device manufacturer might include a transparency requirement in the purchase specification for tubing for an implantable catheter. Such a requirement might be related to the later processing of the tubing into the finished device. To change the supplier of that material, the specification must include a transparency requirement, and the device manufacturer's design validation, as required by the GMP regulation, must describe the rationale for that transparency requirement. Further, the manufacturer should document that component specifications are

still met and that the performance specifications (characteristics) of the device are not significantly affected.

Materials Changes for In Vitro Diagnostic Products

D.1 Is there a change in performance specifications? Changes in the material used in an IVD can affect the performance of the product and should be assessed as to their impact on safety and effectiveness.

D.1.1 Does the change in performance specifications of the IVD affect its indications for use? A change in the indications for use will likely include a change in the labeling for the IVD. Examples of changes in indications for use that require a new 510(k) are: the expansion of the use of the test to a new population of clinical applications; and the addition of a new matrix for analysis, e.g. for an IVD approved for serum, the addition of use with other matrices. An example of a change in an indication for use not requiring a new 510(k) is the expansion of the use of the test to other equivalent instrumentation beyond that noted in the original submission. (For details on the procedure to be followed for this change, see "FDA Guidance for Review of Primary and Secondary Reagents.")¹² *It should be noted that a reduction in the indications for use for an IVD will not always trigger the need for a 510(k).*

D.1.2 Does the change in the performance specifications of the IVD mean that new clinical data will be necessary to establish the safety and effectiveness of the device for the purpose of demonstrating substantial equivalence? An example of a change where a new 510(k) would be required is if the material change results in a change in cut-off. In that case, clinical testing would be required, and the results should be part of the new 510(k). (Note that clinical testing refers to testing of clinical samples either at the manufacturing site or at sites of intended use.) An example where new clinical data are necessary, but a new 510(k) is not necessary, is when the testing of the new material, using splits of patient specimens, is necessary to compare the new material to a previously used material.

D.1.3 Does the change in the performance specifications of the IVD mean that new clinical data will be necessary to show continuing conformance of the device to a recognized standard? Voluntary standards such as those developed by the National Committee of Clinical Laboratory Standards (NCCLS), the National Cholesterol Educational Program and other professional groups may be the basis of a substantial equivalence determination for an IVD.

Deviation of IVD performance specifications from the performance values of the standard may indicate that substantial equivalence of the device is in question.

- D.1.4** Do the results of the design validation performed as a result of this change in materials raise new questions of safety and effectiveness? As noted above, design validation is required when changes are made to any device, including an IVD. The results of such a validation showing that questions of safety and effectiveness have been raised may indicate that the performance of the device is not known or well established, and a 510(k) may be necessary.
- D.2** Does the change in material alter the operating principle of the IVD? Examples of changes in materials that alter the operating principle of the device and would routinely require a 510(k) are: changes from liquid to solid reagent; change from an RIA to a non-RIA; changes in the source and type of an antibody, e.g. from one animal species to another or from polyclonal to monoclonal or vice-versa; change from immunofluorescence to ELISA; and a change in conjugates. Examples of changes that might affect the operating principle of the IVD are changes in reaction components or materials such as calibration materials and quality control materials or changes in methods such as specimen pretreatment, incubation times and temperatures. If these result in changes in the reporting of performance in labeling, they would require a new 510(k). Examples of changes in materials which do not affect the operating principles are changes in preservatives and changes in formulations of the existing materials.

Flowchart Definitions

The following definitions are provided to clarify the meaning of all terms used in the flow chart and to assist in determining when a 510(k) is necessary for a change to an existing device. Wherever possible, existing definitions from the Food, Drug and Cosmetic Act, the medical device regulations or ODE Bluebook memoranda have been used. In some cases, where regulatory definitions are unavailable, we have relied on strict dictionary definitions of terms.

1. Indications for use: An indication for use is "a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended."¹³ The indications include all the labeled patient uses of the device, as for example:

- the condition(s) or disease(s) to be screened, monitored, treated or diagnosed,
- prescription versus over-the-counter use,
- part of the body or type of tissue applied to or interacted with,
- frequency of use, or
- physiological purpose (e.g., removes water from blood, transports blood, etc.).

The indications for use are normally found in the indications section of the labeling, but indications may also be inferred from other parts of the labeling such as the precautions, warnings or the bibliography sections. In some instances, a change in the indications for use may imply a change in the intended use for the device, in which case, the 510(k) for the change would be found not substantially equivalent and a premarket approval application or a reclassification petition would be necessary.¹⁴

2. Labeling: *The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or its containers or wrappers, or (2) accompanying such article.*¹⁵ This can include, among other things, any user or maintenance manuals, as well as advertising and promotional literature.

3. Warnings, precautions and contraindications:

- Warnings describe serious adverse reactions and potential safety hazards that can occur in the proper use or misuse of a device, along with consequent limitations in use and mitigating steps to take if they occur.

- Precautions describe any special care to be exercised by a practitioner or patient for the safe and effective use of a device.
 - Contraindications describe situations in which the device should not be used because the risk of use clearly outweighs any reasonably foreseeable benefits.¹⁶
4. **Documentation**: Recording the results of applying the model to proposed changes in a device. Consideration of each decision point should be recorded, as well as the final conclusions reached. A copy of this documentation should be maintained for future reference.
 5. **Control Mechanism**: The manner by which the actions of a device are directed. An example of a change in control mechanism would be the replacement of an electro-mechanical control with a microprocessor control.
 6. **Operating Principle**: The mode of operation or mechanism of action through which a device fulfills (or achieves) its intended use. An example of a change in operating principle would be using a new algorithm to compress images in a picture archiving and communications system.
 7. **Energy Type or Character**: The type of power input to or output from the device. Examples of a change in energy type or character would be a change from AC to battery power (input) or a change from ionizing radiation to ultrasound to measure a property of the body (output).
 8. **Environmental Specifications**: The (range of) acceptable levels of environmental parameters or operating conditions under which the device will perform safely and effectively. Examples of changes in environmental specifications would be expanding the acceptable temperature range in which the device will operate properly or hardening the device to significantly higher levels of electromagnetic interference.
 9. **Performance Specifications**: The performance characteristics of a device as listed in device labeling or in finished product release specifications. Some examples of performance specifications are measurement accuracy, output accuracy, energy output level, stability criteria, etc.
 10. **Ergonomics of Patient/User Interface**: The way in which the device and the patient/user are intended to interact. Examples of this would be the various audible or visible alarms intended to alert the user to a hazardous condition, the layout of a control panel, or the mode of presentation of information to the user.

Draft...August 1, 1995

11. **Packaging**: Any wrapping, containers, etc., used to protect, to preserve the sterility of, or to group medical devices.

12. **Expiration date**: The date beyond which there are no data to assure that the product may perform safely or effectively.

13. **Method of Sterilization**: The physical or chemical mechanism used to achieve sterility or to achieve a specific sterility assurance level (SAL).

14. **Software**: The set of instructions used to control the actions or output of a medical device, to provide input to or output from a medical device, or to provide the actions of a medical device. This definition includes software that is imbedded or permanently a part of a medical device, software that is an accessory to a medical device, or software that is itself a medical device.

15. **Material Supplier**: The firm supplying the raw material to a finished device manufacturer.

16. **Reuse**: Use of a device more than once on a single patient or on more than one patient. Actions necessary for reuse of a device may include instructions for assembly/disassembly, on-site sterilization or disinfection, etc. This definition does not include the refurbishing or repair of a device for redistribution or resale.

17. **Material Type**: The generic name of the material from which the device is manufactured. (Use the generic name in the biomaterials compendium.) An example of a material type change would be the change from natural latex rubber to synthetic rubber.

18. **Material Formulation**: The base polymer formulation or the alloy, additives, colors, etc., used to establish a property or the stability of the material. This does not include processing aids, mold release agents, residual contaminants, or other manufacturing aids that are not intended to be a part of the material. An example of a change in material formulation would be a change from a series 300 stainless steel to a series 400 stainless steel.

19. **Dimensional Specifications**: The physical size and shape of the device. Such specifications may include the length, width, thickness or diameter of a device, as well as the location of a part or component of the device.

Draft...August 1, 1995

20. **Implant:** A device which is intended to reside within a surgically or naturally formed channel or cavity of the human body for a period of 30 days or more (excluding dental restoration materials).

21. **In Vitro Device:** *Those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.*¹⁷

22. **Change:** As used in the model, this means a proposed change and not the impact of a proposed change. Important impacts of a proposed change are identified on the flow chart. For example, a manufacturer may propose a change in method of sterilization. This change could impact on performance specifications because of potential chemical or physical damage to the device. The proposed change (in method of sterilization) is the change that must be used in the model.

Draft...August 1, 1995

1. Section 520(f) of the Food, Drug and Cosmetic Act.
2. ODE Bluebook Memorandum No. K86-3 (June 30, 1986), "Premarket Review Notification Program."
3. "Kit Certification and Information for Kit 510(k)s," memorandum to manufacturers(?), June 7, 1993.
4. See, for example, ODE Bluebook Memoranda K86-3, K90-1, etc, as well as device-specific guidance documents.
5. "Premarket Notification Document (510(k)) for Daily Wear Contact Lenses," May 12, 1994.
6. 21 CFR Part 820.
7. "Write It Right, Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care," HHS Publication (FDA) 93-4258, August 1993.
8. Section 513(i)(1) of the Food, Drug and Cosmetics Act.
9. 21 CFR 807.81(a)(3).
10. (Reference to draft guidance on Kits).
11. ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing.
12. "FDA Guidance for Review of Primary and Secondary Reagents."
13. 21 CFR 814.20(b)(3)(i).
14. ODE Bluebook Memorandum K86-3, "Guidance on the CDRH Premarket Notification Review Program."
15. Section 201(m) of the Food, Drug and Cosmetic Act.
16. For further information see ODE Bluebook Memorandum G91-1, "Device Labeling Guidance.
17. 21 CFR 809.3(a).

WHEN TO FILE A 510(K) AFTER A CHANGE TO AN APPROVED DEVICE

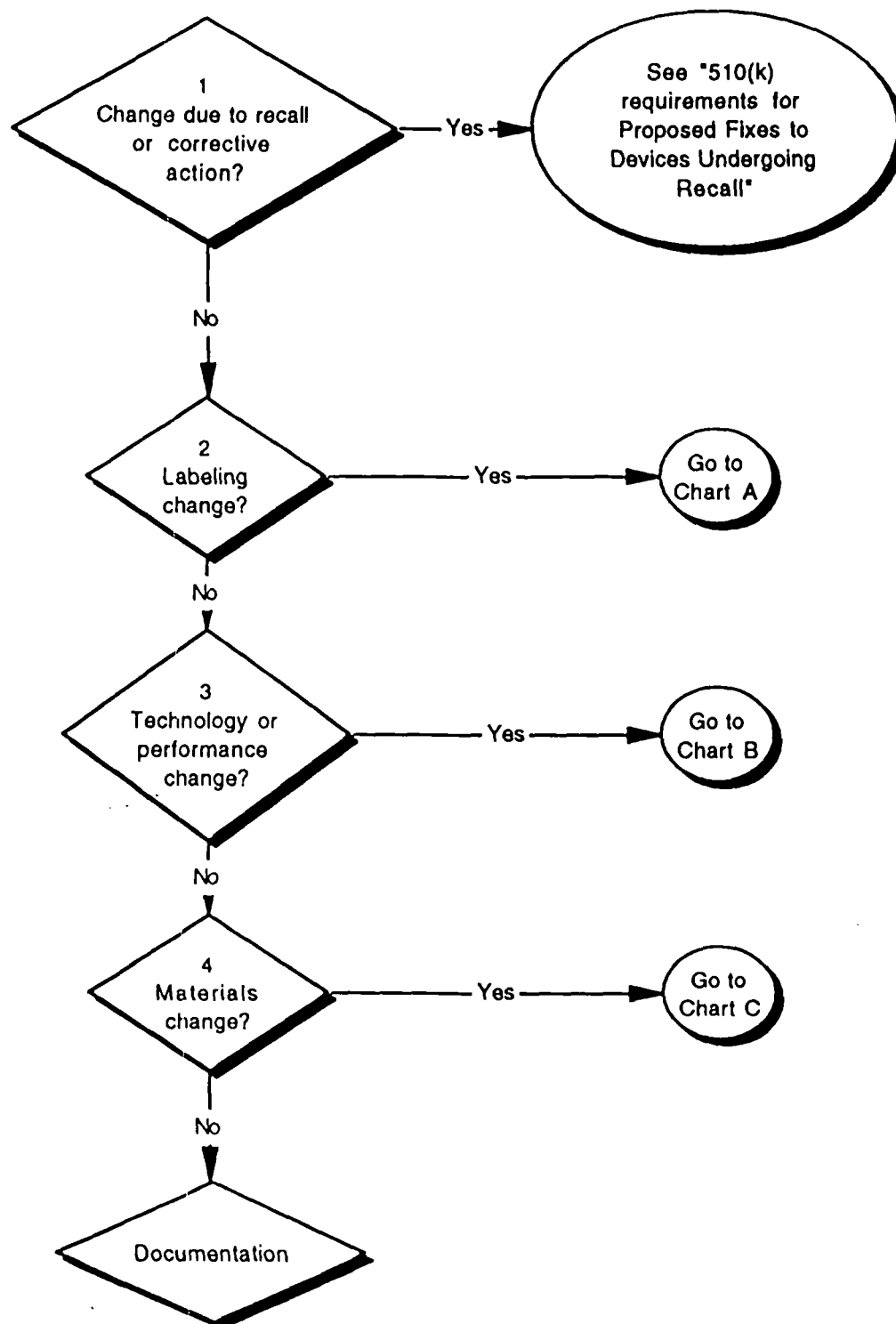


Figure 1

CHART A - IS IT A LABELING CHANGE?

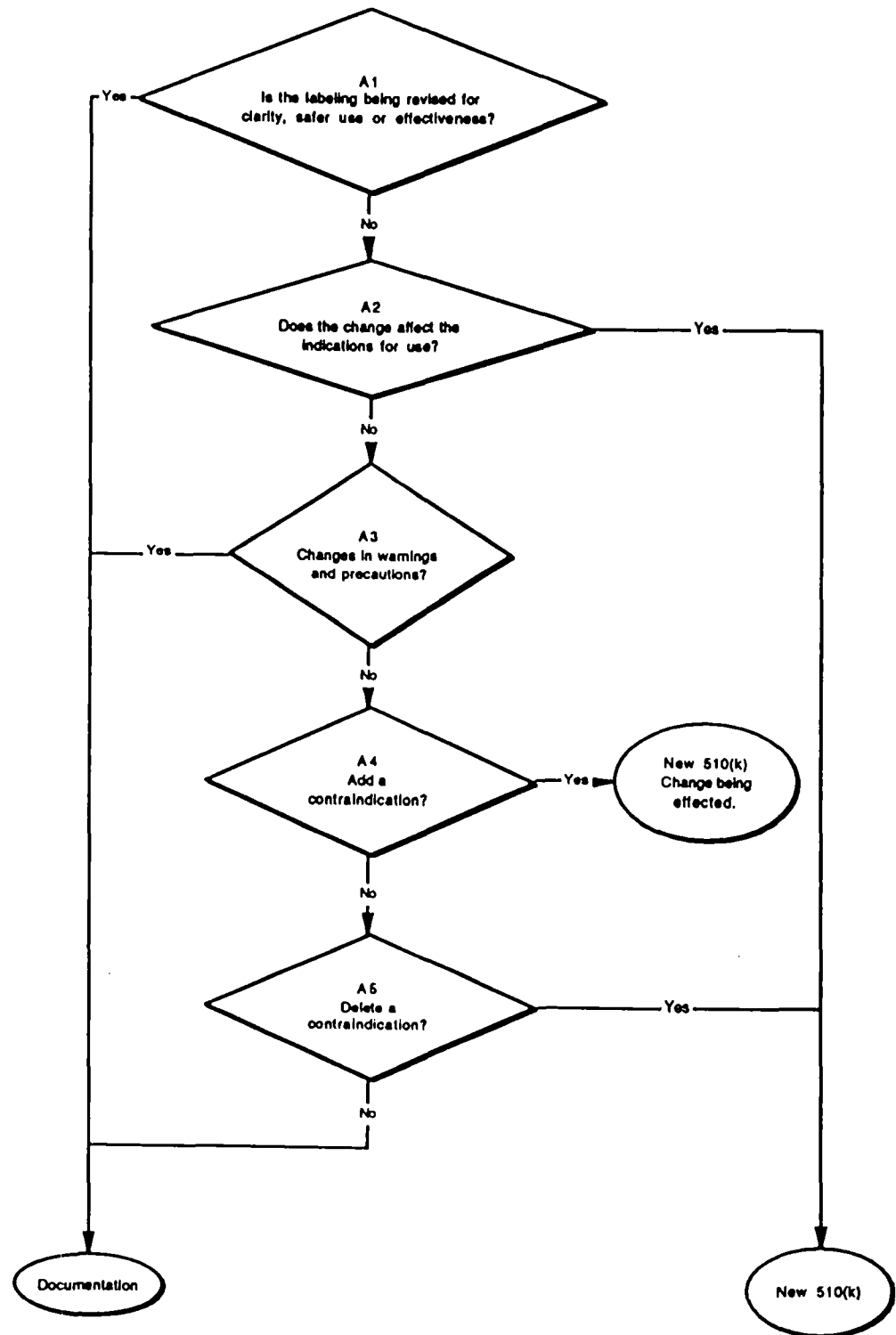


Figure 2

DRAFT...August 1, 1995

CHART B - IS IT A TECHNOLOGY OR PERFORMANCE CHANGE?

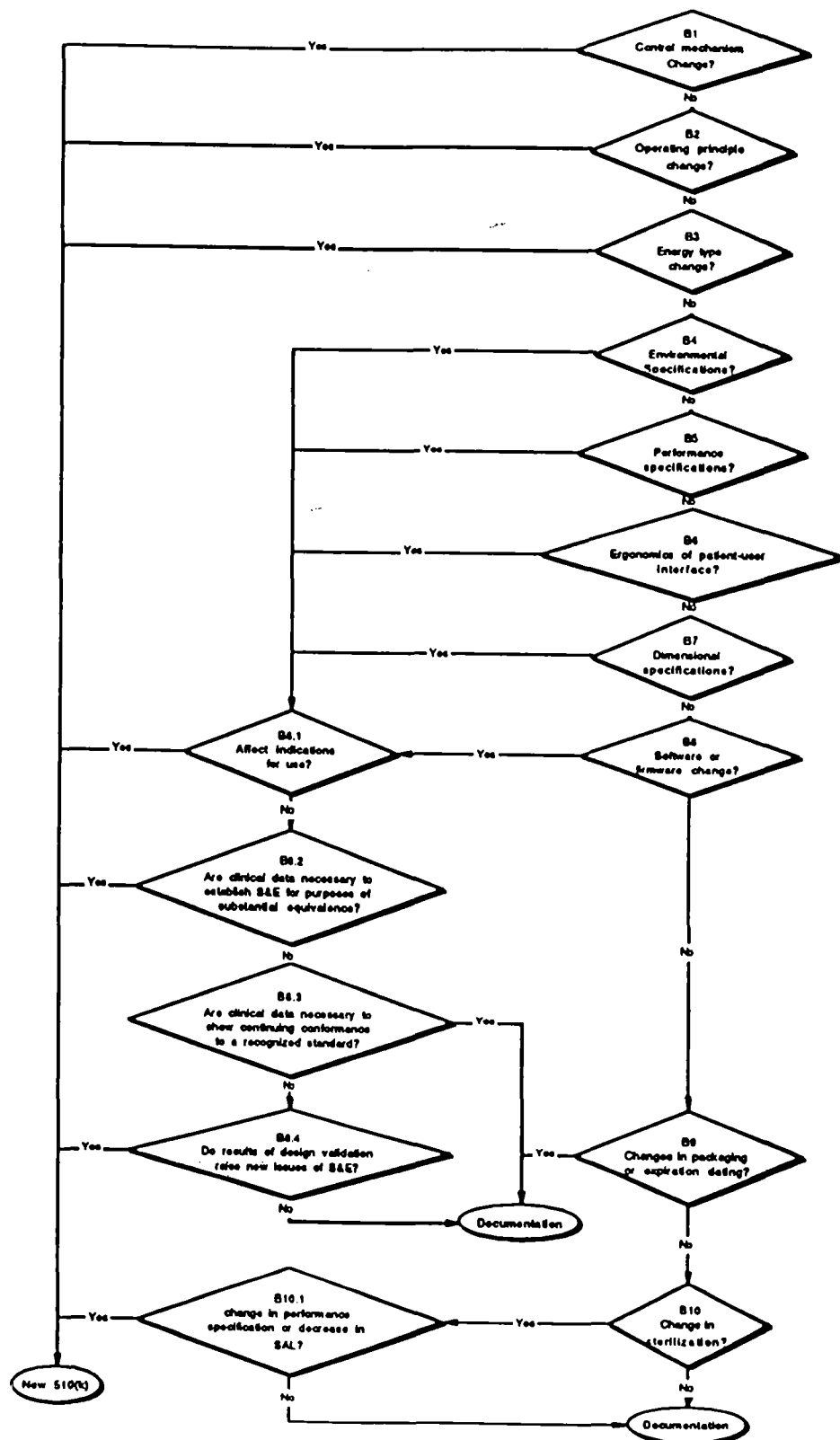


Figure 3

CHART C - IS IT A MATERIALS CHANGE?

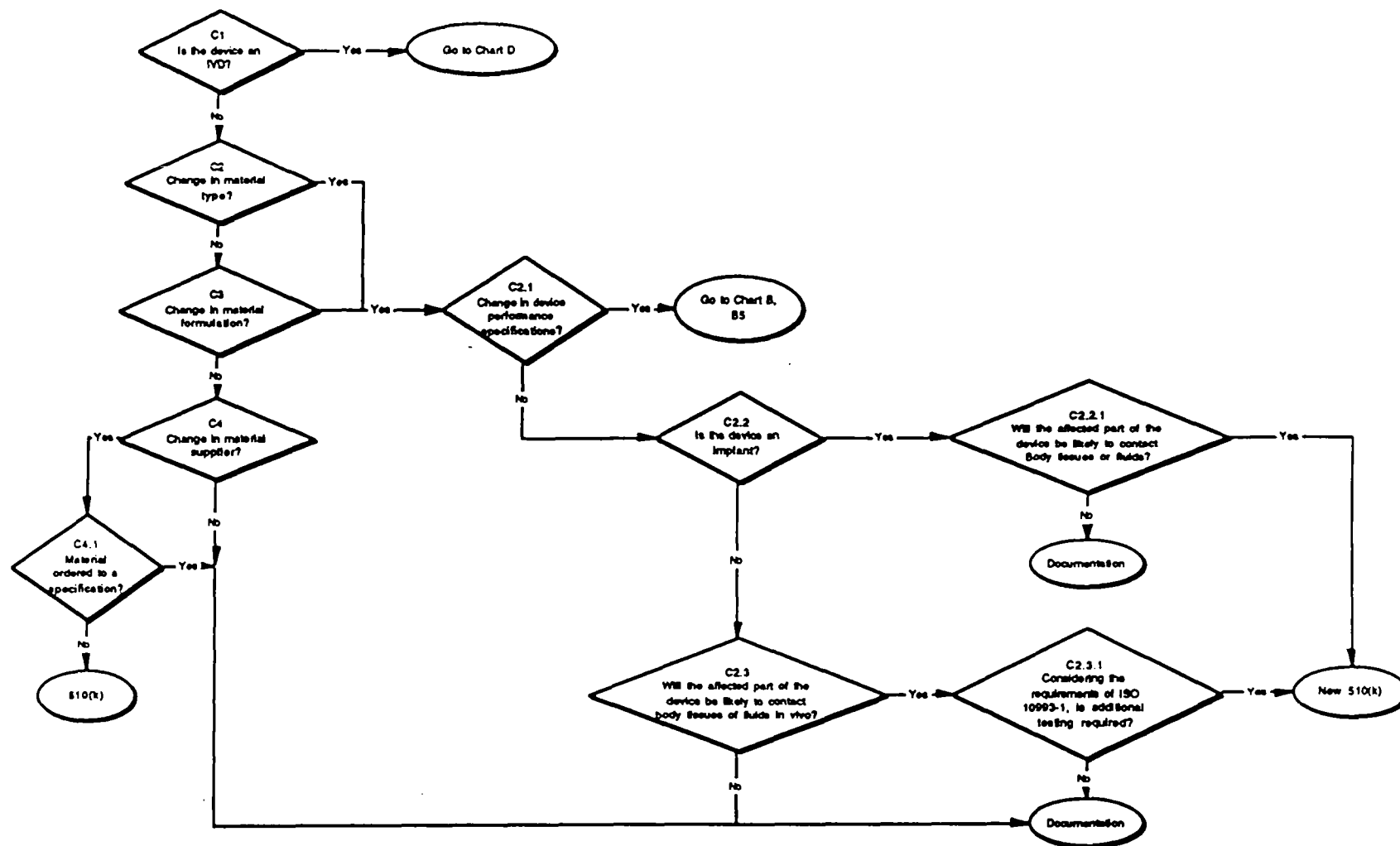


Figure 4

CHART D - MATERIALS CHANGE FOR AN IVD

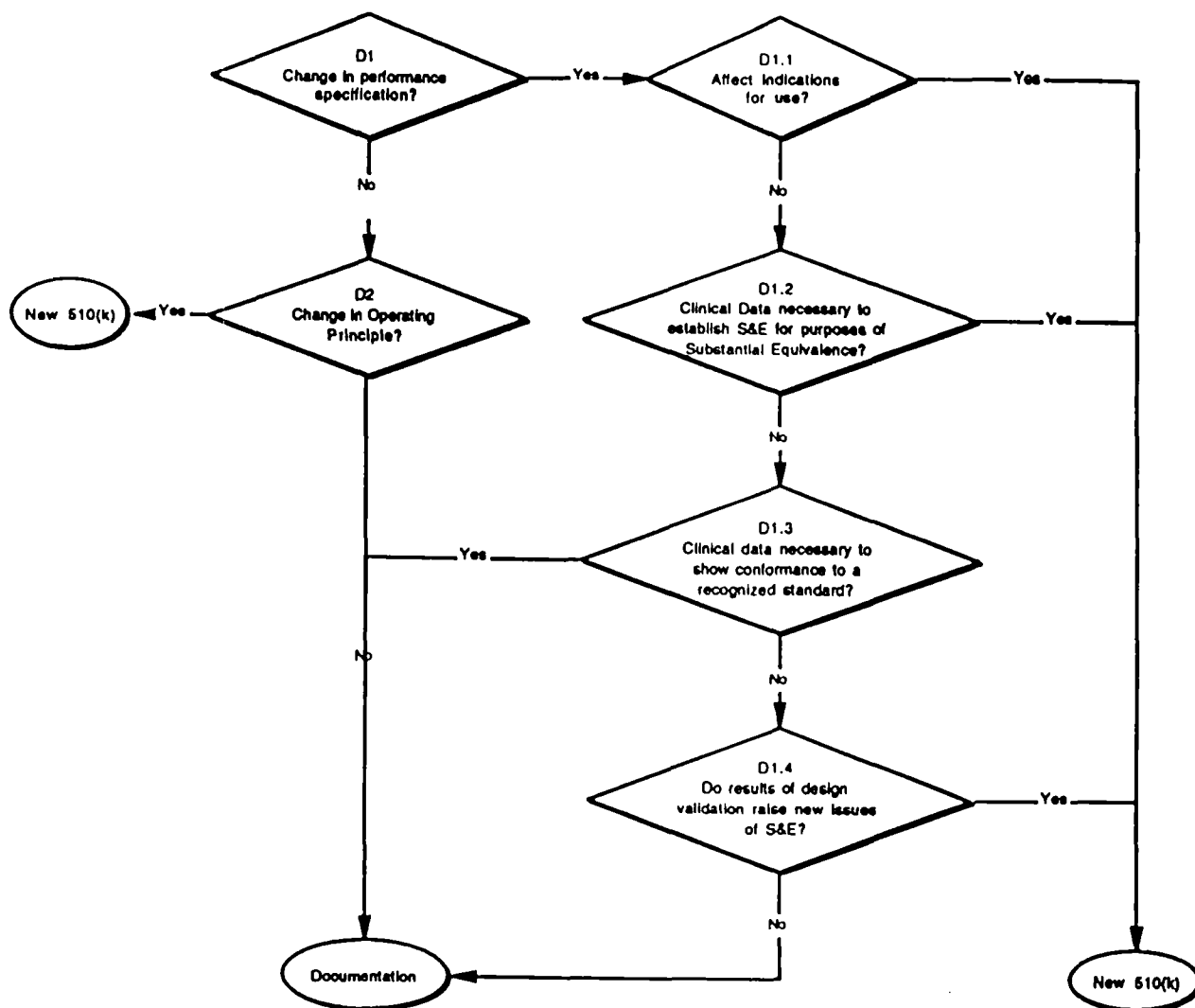


Figure 5

Draft...August 1, 1995

**APPENDIX: DRAFT CONTROLLED VOCABULARY FROM THE FDA BIOMATERIALS
COMPENDIUM**

Material Class

metal
polymer
ceramic
composite
biological origin

Material Subclasses

Metals

stainless steels
co & ni alloys
titanium alloys
zirconium alloys
tantalum alloys
precious metals
amalgams

Polymers

thermoplastics
thermoset/elastomers
absorbable
adhesives
fluids

Ceramics

Al compounds
Ti compounds
Zr compounds
Ca compounds
carbons
glasses

Composites

polymer matrix
metal matrix
ceramic matrix

Biologic Origin

allograft
xenograft
engineered tissues
biomolecules

Draft...August 1, 1995

METALS

Generic Material Names

Stainless Steels

316L FeCrNiMo
nitrogen strengthened
ferritic ppt hardened
?martensitic, ptt hardened

Co & Ni Alloys

CoCrMo period
CoCrWNI
CoNiCrMo
CoNiCrMoWFe
CoCrNiMoFe

Ti Alloys

CpTi (grade 1-4)
Ti 6Al 4V
Ti 6Al 7Nb
Ti 5Al 2.5 Fe
Ti 3.8Al15Mo5Zr
Ti 13Nb13Zr
Ti 12Mo6Zr2Fe
Ti 15Mo2.8Nb.2Si
NiTi alloy

Zr Alloys
Zr2.5Nb

Ta Alloys
unalloyed Ta

Precious/Noble
gold
silver
platinum
palladium
iridium
Pt/Ir

Amalgams

*Ag-Hg amalgams

Draft...August 1, 1995

POLYMERIC MATERIALS

Thermoplastic

acetals
*acrylic, powder/liquid
acrylic, PMMA
acrylic, hydrogels
fluorocarbons
polyamides (nylons)
poly(aryl)ether ketones
poly(aryl)sulfones
polycarbonate
parylene
polyesters (PET, PBT)
polyethylene
polyethylene, UHMWPE
polyimides
polypropylene
polystyrene
polyurethane
polyvinyl alcohol
polyvinyl chloride PVC
polyvinylidene chloride

PEO hydrogel

Adhesives

cyanocrylates
acrylic based
epoxy
silicone

Thermoset/Elasto

butyl
epoxy
hydrogel based
natural hevea
polyesterurethanes
polyetherurethanes
polyurethanes (other)
polyisoprene
rubbermodified acrylic
silicone gel
silicone elastomer
bis/GMA

Fluids

polyvinylpyrrolidone
silicone (PDMS)

Absorbable

polyesters
polyethers
polyanhydrides
polyorthoesters
polyetheramide

copolymers

Draft...August 1, 1995

CERAMICS and COMPOSITES

CERAMICS

Al Compounds

polycrystalline alumina
sapphire
ruby

Ti Compounds

titanium dioxide
TiN
titanium carbide

Zr Compounds

zirconium dioxide
MG-PSZ
Y-TZP
CaO stabilized

Ca Compounds

Beta-TCP
Ca phosphate
Ca hydroxyphosphate
calcium aluminate
gypsum
HA/TCP
hydroxylapatite

Carbons

fibers
graphite
LTI pyrolytic
LTI-Si alloy
ULTI pyrolytic
vapor deposited
vitreous

Glasses

bioactive glass
silica based

COMPOSITES

Polymer Matrix

CFR epoxy
CFR poly(etherketones)
CFR poly(imide)
CFR Poly(sulfone)
glass reinforced
ceramic particle reinforced
metal fiber reinforced
PUIPC
*PTFE composites
CFR UHMWPE
bis/GMA composites
urethanedimethacrylate

Metal Matrix

*Ta-Eigiloy wire
Ag-MP35 I?

Ceramic Matrix

carbon-carbon
zinc phosphate cement
porcelains
*zinc oxide eugenol
glass ionomer cements

zinc polycarboxylate cement

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

E

Divider Title: _____

2. Labeling Requirements

The flammability standard became effective on May 1, 1975, and is applicable to sleepwear in sizes 7 through 14 manufactured after that date. Sleepwear in sizes 7 through 14 manufactured before the effective date of the standard is not subject to the standard, and could be sold after May 1, 1975, without violating the standard or the FFA. To help consumers identify sleepwear in sizes 7 through 14 manufactured to comply with the standard, the Commission required complying sleepwear in sizes 7 through 14 manufactured between May 1, 1975, and May 1, 1978, to be labeled with the statement: "Flame-resistant, U.S. Standard FF 5-74." 16 CFR 1616.6(b).

In 1975, the Commission issued regulations for labeling, recordkeeping, and retail display of children's sleepwear in sizes 7 through 14. 16 CFR Part 1616, Subpart B. See the Federal Register notice of April 1, 1975 (40 FR 14584). These regulations required complying sleepwear in sizes 7 through 14 manufactured between May 1, 1975, and May 1, 1978 to be labeled with the statement "Flame-resistant, U.S. Standard FF 5-74." 16 CFR 1616.31(b)(8). This is the same statement required by section 1616.6(b) of the standard.

3. Requirements for Retail Display

The regulations issued in 1975 also included a requirement to segregate complying and noncomplying sleepwear offered for sale at retail stores. The purpose of this requirement was to help consumers distinguish noncomplying sleepwear manufactured before May 1, 1975, from complying sleepwear manufactured after that date.

The Commission required any person who sold noncomplying sleepwear in sizes 7 through 14 to physically segregate it from complying sleepwear in those sizes. 16 CFR 1616.31(c). The Commission also required complying sleepwear in sizes 7 through 14 sold at the same location as noncomplying sleepwear to be identified by a sign stating: "Flame resistant. Complies with the Standard for the Flammability of Children's Sleepwear (FF 5-74)." Noncomplying sleepwear in those sizes was required to be identified by a sign stating: "Flammable. Does Not Meet Standard for the Flammability of Children's Sleepwear (FF 5-74)." *Id.*

B. Revocation

Since May 1, 1975, all sleepwear in sizes 7 through 14 must be manufactured to comply with the standard. Noncomplying sleepwear in

sizes 7 through 14 has not been legally manufactured since that date. The labeling and retail display requirements described above do not apply to sleepwear sold today or that will be sold in the future. Accordingly, the Commission is revoking (i) the labeling requirements in section 1616.6(b) of the standard and in section 1616.31(b)(8) of the enforcement regulations, and (ii) the requirements for retail display of complying and noncomplying sleepwear in section 1616.31(c) of those regulations.

Generally, the Administrative Procedure Act (APA) (5 U.S.C. 553) requires agencies to publish a notice of proposed rulemaking and provide opportunity for public comment before issuing or revoking a regulation. However, the APA provides at 5 U.S.C. 553(b)(3) that the requirement for a notice of proposed rulemaking is not applicable when the agency finds for good cause that notice of proposed rulemaking and public participation are "impracticable, unnecessary, or contrary to the public interest."

The Commission finds for good cause that notice of proposed rulemaking and public participation are unnecessary because no sleepwear in sizes 7 through 14 offered for sale now or that will be offered for sale in the future is subject to the requirements of 16 CFR 1616.6(b), 1616.31(b)(8), or 1616.31(c). The rules being revoked have no effect on the rights or duties of any persons who manufacture, sell, or purchase sleepwear in sizes 7 through 14. Providing notice of proposed rulemaking and opportunity for submission of written comments on the proposal would be a meaningless procedure in this case.

The APA also requires at 5 U.S.C. 553(d) that a substantive rule must be published at least 30 days before its effective date unless the agency finds for good cause that such delay is not needed. Again, because no sleepwear in sizes 7 through 14 offered for sale now or in the future is subject to the rules being revoked, the Commission finds for good cause that a delayed effective date is unnecessary. Consequently, this revocation shall become effective immediately.

C. Conclusion

Under the authority of section 553 of the Administrative Procedure Act and sections 4 and 5 of the Flammable Fabrics Act, the Commission hereby amends title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, Part 1616 to read as follows:

PART 1616—[AMENDED]

Subpart A—[Amended]

1. The authority for Part 1616, Subpart A, continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569-70; 15 U.S.C. 1193.

§ 1616.6 [Removed and reserved]

2. Section 1616.6(b) is revoked, removed and reserved.

Subpart B—[Amended]

3. The authority for Part 1616, Subpart B, continues to read as follows:

Authority: Sec. 5, 67 Stat. 112-13, as amended, 81 Stat. 571; 15 U.S.C. 1194.

§ 1616.3 [Removed and reserved]

4. Sections 1616.31 (b)(6) and (c) are removed and reserved.

(5 U.S.C. 553; 15 U.S.C. 1193, 1194)

Dated: December 15, 1995.

Sadye E. Dunn,
Secretary, Consumer Product Safety
Commission.

[FR Doc. 96-421 Filed 1-11-96; 2:00 pm]

BILLING CODE 6356-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. 95N-0139]

RIN 0910-AA65

Medical Devices; Reclassification and Exemption From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying 111 generic types of class II devices into class I based on new information respecting such devices. FDA is also exempting the 111 generic types of devices, and 11 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. The exemptions allow

the agency to make better use of its resources and thus better serve the public. These devices will remain subject to current good manufacturing practice (CGMP) regulations and other general controls. This rulemaking is part of the President's and Vice President's Reinventing Government effort.

DATES: Effective February 15, 1996. Beginning on February 15, 1996, all device manufacturers who have 510(k) submissions pending FDA review for devices falling within a generic category which is subject to this rule, will receive a letter stating that the device is exempt from the premarket notification requirements of the act.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 28, 1995 (60 FR 38902), FDA issued a proposed rule to reclassify 112 generic types of class II devices into class I based on new information respecting such devices and to exempt the 112 generic types of devices, and 12 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. Interested persons were given until October 11, 1995, to comment on the proposed rule.

II. Comments

During the comment period, FDA received three comments requesting that various devices be added to the list of devices that the agency was proposing to reclassify into class I and/or exempt from the requirement of premarket notification. FDA is considering these comments and will address them in a future issue of the Federal Register.

FDA also received a comment stating that the proposed reclassification and exemption for endoscope and accessories (21 CFR 876.1500) was too narrow. According to this comment, the reclassification and exemption for endoscope and accessories should be expanded to include additional endoscope accessories which the comment felt meets the reclassification and exemption criteria. FDA is finalizing the endoscope and accessories reclassification and exemption as proposed. However, FDA is considering expanding the reclassification and exemption for endoscope and accessories to include additional endoscope accessories and FDA will

address this device in a future issue of the Federal Register.

FDA received three comments questioning the appropriateness of the proposed reclassification and exemption for scented or scented deodorized menstrual pads (21 CFR 884.5425) and the proposed exemption for unscented menstrual pads (21 CFR 884.5435). All three comments requested that the "made from cotton or rayon" limitation placed upon the proposed reclassification into class I and the exemption from the requirement of premarket notification be revised. In addition, two of the comments questioned the proposed requirements for safety testing. FDA is deferring action on these two devices in order to review these comments more closely and to reevaluate whether the devices should be reclassified and/or exempted from the requirement of premarket notification, with limitations. The agency will address these devices in a future issue of the Federal Register.

III. Conclusion

FDA received no comments opposing the reclassification into class I of 111 of the 112 generic types of devices included in the proposed rule. Moreover, the agency did not receive comments opposing the proposed exemption from the requirements of premarket notification for 111 of these 112 generic types of devices, and 11 already classified generic types of class I devices. For 111 of the 112 devices proposed for reclassification into class I, the agency has concluded, based on new information respecting such devices as described in the proposed rule, that general controls will provide reasonable assurance of the safety and effectiveness of these devices. For 122 of the 124 devices for which exemptions have been proposed (including the 111 device types being reclassified), FDA has concluded that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. Thus, FDA is finalizing the reclassification of 111 devices and the exemption from premarket notification for 122 devices, including the 111 devices being reclassified and 11 of the devices already classified in class I. All of these devices remain subject to CGMP requirements and other general controls under the statute.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or

cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment or an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule would reduce a regulatory burden by exempting manufacturers of devices subject to the rule from the requirements of premarket notification, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Parts 862, 868, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892 are amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 862.2230 is amended by revising paragraph (b) to read as follows:

§ 862.2230 Chromatographic separation material for clinical use.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

3. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 866.2160 is amended by revising paragraph (b) to read as follows:

§ 866.2160 Coagulase plasma.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

5. Section 866.3720 is amended by revising paragraph (b) to read as follows:

§ 866.3720 *Streptococcus* spp. exoenzyme reagents.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

6. Section 866.5520 is amended by revising paragraph (b) to read as follows:

§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

7. Section 866.5530 is amended by revising paragraph (b) to read as follows:

§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

8. Section 866.5860 is amended by revising paragraph (b) to read as follows:

§ 866.5860 Total spinal fluid immunological test system.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 868—ANESTHESIOLOGY DEVICES

9. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

10. Section 868.1100 is amended by revising paragraph (b) to read as follows:

§ 868.1100 Arterial blood sampling kit.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

11. Section 868.1575 is amended by revising paragraph (b) to read as follows:

§ 868.1575 Gas collection vessel.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

12. Section 868.1870 is amended by revising paragraph (b) to read as follows:

§ 868.1870 Gas volume calibrator.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

13. Section 868.1975 is amended by revising paragraph (b) to read as follows:

§ 868.1975 Water vapor analyzer.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

14. Section 868.2300 is amended by revising paragraph (b) to read as follows:

§ 868.2300 Bourdon gauge flowmeter.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

15. Section 868.2320 is amended by revising paragraph (b) to read as follows:

§ 868.2320 Uncompensated thorpe tube flowmeter.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

16. Section 868.2340 is amended by revising paragraph (b) to read as follows:

§ 868.2340 Compensated thorpe tube flowmeter.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

17. Section 868.2350 is amended by revising paragraph (b) to read as follows:

§ 868.2350 Gas calibration flowmeter.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

18. Section 868.2610 is amended by revising paragraph (b) to read as follows:

§ 868.2610 Gas pressure gauge.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

19. Section 868.2620 is amended by revising paragraph (b) to read as follows:

§ 868.2620 Gas pressure calibrator.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

20. Section 868.2700 is amended by revising paragraph (b) to read as follows:

§ 868.2700 Pressure regulator.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

21. Section 868.2875 is amended by revising paragraph (b) to read as follows:

§ 868.2875 Differential pressure transducer.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

22. Section 868.2885 is amended by revising paragraph (b) to read as follows:

§ 868.2885 Gas flow transducer.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

23. Section 868.2900 is amended by revising paragraph (b) to read as follows:

§ 868.2900 Gas pressure transducer.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

24. Section 868.5100 is amended by revising paragraph (b) to read as follows:

§ 868.5100 Nasopharyngeal airway.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

25. Section 868.5110 is amended by revising paragraph (b) to read as follows:

§ 868.5110 Oropharyngeal airway.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

26. Section 868.5240 is amended by revising paragraph (b) to read as follows:

§ 868.5240 Anesthesia breathing circuit.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

27. Section 868.5300 is amended by revising paragraph (b) to read as follows:

§ 868.5300 Carbon dioxide absorbent.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

28. Section 868.5310 is amended by revising paragraph (b) to read as follows:

§ 868.5310 Carbon dioxide absorber.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

29. Section 868.5320 is amended by revising paragraph (b) to read as follows:

§ 868.5320 Reservoir bag.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

30. Section 868.5375 is amended by revising paragraph (b) to read as follows:

§ 868.5375 Heat and moisture condenser (artificial nose).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

31. Section 868.5460 is amended by revising paragraph (b) to read as follows:

§ 868.5460 Therapeutic humidifier for home use.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

32. Section 868.5530 is amended by revising paragraph (b) to read as follows:

§ 868.5530 Flexible laryngoscope.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

33. Section 868.5540 is amended by revising paragraph (b) to read as follows:

§ 868.5540 Rigid laryngoscope.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

34. Section 868.5550 is amended by revising paragraph (b) to read as follows:

§ 868.5550 Anesthetic gas mask.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

35. Section 868.5570 is amended by revising paragraph (b) to read as follows:

§ 868.5570 Nonbreathing mask.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

36. Section 868.5580 is amended by revising paragraph (b) to read as follows:

§ 868.5580 Oxygen mask.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

37. Section 868.5590 is amended by revising paragraph (b) to read as follows:

§ 868.5590 Scavenging mask.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

38. Section 868.5600 is amended by revising paragraph (b) to read as follows:

§ 868.5600 Venturi mask.

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

39. Section 868.5770 is amended by revising paragraph (b) to read as follows:

§ 868.5770 Tracheal tube fixation device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

40. Section 868.5780 is amended by revising paragraph (b) to read as follows:

§ 868.5780 Tube introduction forceps.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

41. Section 868.5790 is amended by revising paragraph (b) to read as follows:

§ 868.5790 Tracheal tube stylet.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

42. Section 868.5810 is amended by revising paragraph (b) to read as follows:

§ 868.5810 Airway connector.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

43. Section 868.5820 is amended by revising paragraph (b) to read as follows:

§ 868.5820 Dental protector.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

44. Section 868.5860 is amended by revising paragraph (b) to read as follows:

§ 868.5860 Pressure tubing and accessories.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

45. Section 868.5975 is amended by revising paragraph (b) to read as follows:

§ 868.5975 Ventilator tubing.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

46. Section 868.5995 is amended by revising paragraph (b) to read as follows:

§ 868.5995 Tee drain (water trap).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

47. Section 868.6400 is amended by revising paragraph (b) to read as follows:

§ 868.6400 Calibration gas.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

48. Section 868.6820 is amended by revising paragraph (b) to read as follows:

§ 868.6820 Patient position support.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

49. Section 868.6885 is amended by revising paragraph (b) to read as follows:

§ 868.6885 Medical gas yoke assembly.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 870—CARDIOVASCULAR DEVICES

50. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

51. Section 870.2390 is amended by revising paragraph (b) to read as follows:

§ 870.2390 Phonocardiograph.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

52. Section 870.2600 is amended by revising paragraph (b) to read as follows:

§ 870.2600 Signal isolation system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

53. Section 870.2620 is amended by revising paragraph (b) to read as follows:

§ 870.2620 Line isolation monitor.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

54. Section 870.2640 is amended by revising paragraph (b) to read as follows:

§ 870.2640 Portable leakage current alarm.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

55. Section 870.2810 is amended by revising paragraph (b) to read as follows:

§ 870.2810 Paper chart recorder.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

56. Section 870.3650 is amended by revising paragraph (b) to read as follows:

§ 870.3650 Pacemaker polymeric mesh bag.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

57. Section 870.3670 is amended by revising paragraph (b) to read as follows:

§ 870.3670 Pacemaker charger.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

58. Section 870.3690 is amended by revising paragraph (b) to read as follows:

§ 870.3690 Pacemaker test magnet.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

59. Section 870.3935 is amended by revising paragraph (b) to read as follows:

§ 870.3935 Prosthetic heart valve holder.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

60. Section 870.3945 is amended by revising paragraph (b) to read as follows:

§ 870.3945 Prosthetic heart valve sizer.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 872—DENTAL DEVICES

61. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

62. Section 872.1840 is amended by revising paragraph (b) to read as follows:

§ 872.1840 Dental X-ray position indicating device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

63. Section 872.1850 is amended by revising paragraph (b) to read as follows:

§ 872.1850 Lead-lined position indicator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

64. Section 872.4630 is amended by revising paragraph (b) to read as follows:

§ 872.4630 Dental operating light.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

65. Section 872.6390 is amended by revising paragraph (b) to read as follows:

§ 872.6390 Dental floss.

(b) *Classification.* Class I. If the device is made of inert materials and is not coated or impregnated with chemicals intended to provide a therapeutic benefit or interact with tissues of the oral cavity, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

PART 874—EAR, NOSE, AND THROAT DEVICES

66. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

67. Section 874.1060 is amended by revising paragraph (b) to read as follows:

§ 874.1060 Acoustic chamber for audiometric testing.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

68. Section 874.1080 is amended by revising paragraph (b) to read as follows:

§ 874.1080 Audiometer calibration set

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

69. Section 874.4140 is amended by revising paragraph (b) to read as follows:

§ 874.4140 Ear, nose, and throat bur.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

70. Section 874.4175 is amended by revising paragraph (b) to read as follows:

§ 874.4175 Nasopharyngeal catheter.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

71. Section 874.4350 is amended by revising paragraph (b) to read as follows:

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

72. Section 874.4770 is amended by revising paragraph (b) to read as follows:

§ 874.4770 Otoscope.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when used in the external ear canal.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

73. The authority citation for 21 CFR part 876 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

74. Section 876.1075 is amended by revising paragraph (b) to read as follows:

§ 876.1075 Gastroenterology-urology biopsy instrument.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the biopsy forceps cover and the non-electric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

75. Section 876.1400 is amended by revising paragraph (b) to read as follows:

§ 876.1400 Stomach pH electrode.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

76. Section 876.1500 is amended by revising paragraph (b) to read as follows:

§ 876.1500 Endoscope and accessories.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

77. Section 876.1800 is amended by revising paragraph (b) to read as follows:

§ 876.1800 Urine flow or volume measuring system.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the disposable, nonelectrical urine flow rate measuring device, and nonelectrical urinometer. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

78. Section 876.4590 is amended by revising paragraph (b) to read as follows:

§ 876.4590 Interlocking urethral sound.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

79. Section 876.4890 is amended by revising paragraph (b) to read as follows:

§ 876.4890 Urological table and accessories.

(b) *Classification.* (1) Class II (performance standards) for the electrically powered urological table and accessories.

(2) Class I for the manually powered table and accessories, and for stirrups for electrically powered table. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

80. Section 876.5090 is amended by revising paragraph (b) to read as follows:

§ 876.5090 Suprapubic urological catheter and accessories.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

81. Section 876.5130 is amended by revising paragraph (b) to read as follows:

§ 876.5130 Urological catheter and accessories.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the ureteral stylet (guidewire), stylet for gastro-urological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

82. Section 876.5450 is amended by revising paragraph (b) to read as follows:

§ 876.5450 Rectal dilator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

83. Section 876.5520 is amended by revising paragraph (b) to read as follows:

§ 876.5520 Urethral dilator.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

84. Section 876.5540 is amended by revising paragraphs (b)(3) and by adding new paragraph (b)(4) to read as follows:

§ 876.5540 Blood access device and accessories.

(b) *Classification.* * * *
(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section.

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

85. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

86. Section 878.4450 is amended by revising paragraph (b) to read as follows:

§ 878.4450 Nonabsorbable gauze for internal use.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

87. Section 878.4810 is amended by revising paragraph (b) to read as follows:

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

(b) *Classification*. (1) Class II.
(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

88. Section 878.5350 is amended by revising paragraph (b) to read as follows:

§ 878.5350 Needle-type epilator.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

89. Section 878.5910 is amended by revising paragraph (b) to read as follows:

§ 878.5910 Pneumatic tourniquet.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

90. The authority citation for 21 CFR 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

91. Section 880.2720 is amended by revising paragraph (b) to read as follows:

§ 880.2720 Patient scale.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

92. Section 880.2900 is amended by revising paragraph (b) to read as follows:

§ 880.2900 Clinical color change thermometer.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

93. Section 880.5560 is amended by revising paragraph (b) to read as follows:

§ 880.5560 Temperature regulated water mattress.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

94. Section 880.6320 is amended by revising paragraph (b) to read as follows:

§ 880.6320 AC-powered medical examination light.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 882—NEUROLOGICAL DEVICES

95. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

96. Section 882.1410 is amended by revising paragraph (b) to read as follows:

§ 882.1410 Electroencephalograph electrode/lead tester.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

97. Section 882.4325 is amended by revising paragraph (b) to read as follows:

§ 882.4325 Cranial drill handpiece (brace).

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

98. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

99. Section 884.1550 is revised to read as follows:

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).

(a) *Identification*. The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocentesis tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

100. Section 884.1640 is amended by revising paragraph (b) to read as follows:

§ 884.1640 Culoscope and accessories.

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applicator (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (non-inflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

101. Section 884.1690 is amended by revising paragraph (b) to read as follows:

§ 884.1690 Hysteroscope and accessories.

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper,

curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

102. Section 884.1700 is amended by revising paragraph (b) to read as follows:

§ 884.1700 Hysteroscopic insufflator.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter fits which only include accessory instruments which are not used to effect intrauterine access e.g. hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

103. Section 884.1720 is amended by revising paragraph (b) to read as follows:

§ 884.1720 Gynecologic laparoscope and accessories.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applicator (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

104. Section 884.1730 is amended by revising paragraph (b) to read as follows:

§ 884.1730 Laparoscopic insufflator.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter kits which include accessory instruments which are not used to effect intra-abdominal access, Verres needles etc.; and single-use tubing kits used for only intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are

exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

105. Section 884.4530 is amended by revising paragraph (b) to read as follows:

§ 884.4530 Obstetric-gynecological specialized manual instrument.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

106. Section 884.5150 is amended by revising paragraph (b) to read as follows:

§ 884.5150 Nonpowered breast pump.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.

107. Section 884.5900 is amended by revising paragraph (b) to read as follows:

§ 884.5900 Therapeutic vaginal douche apparatus.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I if the device is operated by gravity feed. Devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 886—OPHTHALMIC DEVICES

108. The authority citation for 21 CFR 886 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

109. Section 886.1405 is amended by revising paragraph (b) to read as follows:

§ 886.1405 Ophthalmic trial lens set.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

110. Section 886.1750 is amended by revising paragraph (b) to read as follows:

§ 886.1750 Skiascopic rack.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

111. Section 886.1760 is amended by revising paragraph (b) to read as follows:

§ 886.1760 Ophthalmic refractometer.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

112. Section 886.3200 is revised to read as follows:

§ 886.3200 Artificial eye.

(a) *Identification.* An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if the device is made from the same materials, has the same chemical composition, and uses the same manufacturing processes as currently legally marketed devices.

PART 888—ORTHOPEDIC DEVICES

113. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

114. Section 888.1100 is amended by revising paragraph (b) to read as follows:

§ 888.1100 Arthroscope.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the following manual arthroscopic instruments: cannulas, currettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knotpushers, suture punches, switching rods, and trocars. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

115. Section 888.3000 is amended by revising paragraph (b) to read as follows:

§ 888.3000 Bone cap.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

116. Section 888.5960 is amended by revising paragraph (b) to read as follows:

§ 888.5960 Cast removal instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 890—PHYSICAL MEDICINE DEVICES

117. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

118. Section 890.1575 is amended by revising paragraph (b) to read as follows:

§ 890.1575 Force-measuring platform.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

119. Section 890.1600 is amended by revising paragraph (b) to read as follows:

§ 890.1600 Intermittent pressure measurement system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

120. Section 890.1615 is amended by revising paragraph (b) to read as follows:

§ 890.1615 Miniature pressure transducer.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

121. Section 890.3175 is amended by revising paragraph (b) to read as follows:

§ 890.3175 Flotation cushion.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

122. Section 890.3760 is amended by revising paragraph (b) to read as follows:

§ 890.3760 Powered table.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

123. Section 890.5380 is amended by revising paragraph (b) to read as follows:

§ 890.5380 Powered exercise equipment.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

124. Section 890.5410 is amended by revising paragraph (b) to read as follows:

§ 890.5410 Powered finger exerciser.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

125. Section 890.5660 is amended by revising paragraph (b) to read as follows:

§ 890.5660 Therapeutic massager.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

126. Section 890.5925 is amended by revising paragraph (b) to read as follows:

§ 890.5925 Traction accessory.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

127. Section 890.5940 is amended by revising paragraph (b) to read as follows:

§ 890.5940 Chilling unit.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

128. Section 890.5950 is amended by revising paragraph (b) to read as follows:

§ 890.5950 Powered heating unit.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

129. Section 890.5975 is amended by revising paragraph (b) to read as follows:

§ 890.5975 Therapeutic vibrator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 892—RADIOLOGY DEVICES

130. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

131. Section 892.1700 is amended by revising paragraph (b) to read as follows:

§ 892.1700 Diagnostic X-ray high voltage generator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

132. Section 892.1760 is amended by revising paragraph (b) to read as follows:

§ 892.1760 Diagnostic X-ray tube housing assembly.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

133. Section 892.1770 is amended by revising paragraph (b) to read as follows:

§ 892.1770 Diagnostic X-ray tube mount.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

134. Section 892.1830 is amended by revising paragraph (b) to read as follows:

§ 892.1830 Radiologic patient cradle.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

135. Section 892.1880 is amended by revising paragraph (b) to read as follows:

§ 892.1880 Wall-mounted radiographic cassette holder.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

136. Section 892.5780 is amended by revising paragraph (b) to read as follows:

§ 892.5780 Light beam patient position indicator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

137. Section 892.6500 is amended by revising paragraph (b) to read as follows:

§ 892.6500 Personnel protective shield.

(b) *Classification.* Class I. If the device's labeling specifies the lead equivalence, it is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter.

Dated: January 5, 1996.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 96-418 Filed 1-11-96; 2:00 pm]
BILLING CODE 4160-01-F

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2610 and 2622

Late Premium Payments and Employer Liability Underpayments and Overpayments; Interest Rate for Determining Variable Rate Premium; Amendments to Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This document notifies the public of the interest rate applicable to late premium payments and employer liability underpayments and overpayments for the calendar quarter beginning January 1, 1996. This interest rate is established quarterly by the Internal Revenue Service. This document also sets forth the interest rates for valuing unfunded vested benefits for premium purposes for plan years beginning in November 1995 through January 1996. These interest rates are established pursuant to section 4006 of the Employee Retirement Income Security Act of 1974, as amended. The effect of these amendments is to advise plan sponsors and pension practitioners of these new interest rates.

EFFECTIVE DATE: January 1, 1996.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005-4026; telephone 202-326-4024 (202-326-4179 for TTY and TTD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: As part of title IV of the Employee Retirement Income Security Act of 1974, as amended, the Pension Benefit Guaranty Corporation collects premiums from ongoing plans to support the single-employer and multiemployer insurance programs. Under the single-employer program, the PBGC also collects employer liability from those persons described in ERISA section 4062(a). Under ERISA section 4007 and 29 CFR § 2610.7, the interest rate to be charged on unpaid premiums is the rate established under section 6601 of the

Internal Revenue Code ("Code"). Similarly, under 29 CFR § 2622.7, the interest rate to be credited or charged with respect to overpayments or underpayments of employer liability is the section 6601 rate. These interest rates are published by the PBGC in appendix A to the premium regulation and appendix A to the employer liability regulation.

The Internal Revenue Service has announced that for the quarter beginning January 1, 1996, the interest charged on the underpayment of taxes will be at a rate of 9 percent.

Accordingly, the PBGC is amending appendix A to 29 CFR part 2610 and appendix A to 29 CFR part 2622 to set forth this rate for the January 1, 1996, through March 31, 1996, quarter.

Under ERISA section 4006(a)(3)(E)(iii)(II), in determining a single-employer plan's unfunded vested benefits for premium computation purposes, plans must use an interest rate equal to 80% of the annual yield on 30-year Treasury securities for the month preceding the beginning of the plan year for which premiums are being paid. Under § 2610.23(b)(1) of the premium regulation, this value is determined by reference to 30-year Treasury constant maturities as reported in Federal Reserve Statistical Releases G.13 and H.15. The PBGC publishes these rates in appendix B to the regulation.

The PBGC publishes these monthly interest rates in appendix B on a quarterly basis to coincide with the publication of the late payment interest rate set forth in appendix A. (The PBGC publishes the appendix A rates every quarter, regardless of whether the rate has changed.) Unlike the appendix A rate, which is determined prospectively, the appendix B rate is not known until a short time after the first of the month for which it applies. Accordingly, the PBGC is hereby amending appendix B to part 2610 to add the vested benefits valuation rates for plan years beginning in November of 1995 through January of 1996.

The appendices to 29 CFR parts 2610 and 2622 do not prescribe the interest rates under these regulations. Under both regulations, the appendix A rates are the rates determined under section 6601(a) of the Code. The interest rates in appendix B to part 2610 are prescribed by ERISA section 4006(a)(3)(E)(iii)(II) and § 2610.23(b)(1) of the regulation. These appendices merely collect and republish the interest rates in a convenient place. Thus, the interest rates in the appendices are informational only. Accordingly, the PBGC finds that notice of and public

comment on these amendments would be unnecessary and contrary to the public interest. For the above reasons, the PBGC also believes that good cause exists for making these amendments effective immediately.

The PBGC has determined that none of these actions is a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for these amendments, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 2610

Employee benefit plans, Penalties, Pension insurance, Pensions, and Reporting and recordkeeping requirements.

29 CFR Part 2622

Business and Industry, Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements, and Small businesses.

In consideration of the foregoing, part 2610 and part 2622 of chapter XXVI of title 29, Code of Federal Regulations, are hereby amended as follows:

PART 2610—PAYMENT OF PREMIUMS

1. The authority citation for part 2610 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1306, 1307.

2. Appendix A to part 2610 is amended by adding a new entry for the quarter beginning January 1, 1996, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix A to Part 2610—Late Payment Interest Rates

The following table lists the late payment interest rates under § 2610.7(a) for the specified time periods:

From—	Through—	Interest rate (percent)
January 1, 1996.	March 31, 1996 .	9.00

3. Appendix B to part 2610 is amended by adding to the table of interest rates new entries for premium payment years beginning in November of 1995 through January of 1996, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

statement is made: "Comments to Docket Number 94-NM-207-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94-25-G1 Boeing: Amendment 39-9085. Docket 94-NM-207-AD.

Applicability: Model 747 series airplanes having line numbers 202 through 396 inclusive, equipped with Pratt & Whitney Model JT9D-70 engines, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of a spring beam, which could lead to the loss of an outboard strut, accomplish the following:

(a) Prior to the accumulation of 10,000 total flight cycles or within 30 days after the effective date of this AD, whichever occurs later, perform a detailed visual inspection to detect cracking of the upper, lower, and side surfaces of the spring beam from the root of the clevis lugs to the forward journal, in accordance with Boeing Alert Service Bulletin 747-54A2171, dated October 31, 1994. (Remove the gap covers and fairing access panels to perform this inspection.)

Note 2: The area of inspection is illustrated in Figure 3 of the service bulletin.

(1) If no cracking is detected, repeat the inspection thereafter at intervals not to exceed 300 flight cycles.

(2) If any cracking is detected, prior to further flight, accomplish the requirements of paragraphs (a)(2)(i), (a)(2)(ii), and (a)(2)(iii) of this AD, in accordance with the service bulletin.

(i) Replace the cracked spring beam with a new spring beam.

(ii) Perform the detailed visual inspection required by paragraph (a) of this AD to detect cracking of the other spring beam on the affected strut. Also perform a detailed visual inspection to detect damage of all spring beam support fittings of the affected strut. Prior to further flight, replace any cracked or damaged parts with new parts.

(iii) Repeat the inspection of the surfaces of the spring beam required by paragraph (a) of this AD thereafter at intervals not to exceed 300 flight cycles.

(b) Accomplishment of all of the following actions in accordance with Boeing Overhaul Manual, Section 54-00-01, constitutes terminating action for the requirements of this AD.

(1) Remove the spring beam.

(2) Accomplish a fluorescent dye penetrant inspection.

(3) Zero-time overhaul the spring beam.

(4) Reinstall that spring beam.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA.

Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The inspections and replacement shall be done in accordance with Boeing Alert Service Bulletin 747-54A2171, dated October 31, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, S.W., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, DC.

(f) This amendment becomes effective on December 22, 1994.

Issued in Renton, Washington, on November 30, 1994.

James V. Devany, Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94-29919 Filed 12-6-94; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 854, 865, 868, 870, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892

[Docket No. 94M-0260]

Medical Devices; Exemptions From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting 148 generic types of class I devices from the requirement of premarket notification, with limitations. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. The exemptions allow

the agency to make better use of its resources and thus better serve the public.

DATES: Effective January 6, 1995. Beginning on January 6, 1995, all device manufacturers who have 510(k) submissions pending FDA review for devices falling within a generic category which is subject to this rule, will receive a letter stating that the device is exempt from the premarket notification requirements of the act.

FOR FURTHER INFORMATION CONTACT: Joseph M. Shoenhan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4765 ext. 157.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 21, 1994 (59 FR 37378), FDA issued a proposed rule to exempt 164 generic types of class I devices from the requirement of premarket notification, with limitations. Interested persons were given until October 19, 1994 to comment on the proposed rule.

II. Comments

During the comment period, FDA received comments requesting that various devices be added to the list of devices that the agency was proposing be exempt from the requirement of premarket notification. The agency also received comments requesting that existing exemptions from the requirement of premarket notification for several devices, when made of certain materials, be expanded to include all devices within the classification, regardless of material composition. FDA is considering these comments and will address them in a future issue of the Federal Register.

Several comments requested that certain devices proposed for exemption from premarket notification also be exempted from the requirements of current good manufacturing practices (CGMP's) and records and reports. FDA has decided not to grant these additional exemptions at this time. Pursuant to 21 CFR 820.1(d), any person petitioning for an exemption from any device CGMP requirement is required to follow the procedures set forth in 21 CFR 10.30. Accordingly, the devices listed in this final rule as exempt from premarket notification continue to be subject to applicable CGMP requirements. FDA believes that compliance with CGMP's is necessary in order to ensure adequate protection of the public health.

III. Conclusion

Several comments questioned the appropriateness of the proposed exemptions for a small number of the devices. In addition, FDA is reconsidering the appropriateness or scope of the proposed exemptions for several devices included in the proposed rule. Therefore, FDA is deferring action on the following 16 devices in order to review these comments and to reevaluate whether certain of the devices should be exempted from the requirement of premarket notification.

TABLE 1

CFR section	Device
862.2270 ..	Thin-layer chromatography system for clinical use.
862.2310 ..	Clinical sample concentrator.
862.2320 ..	Beta or gamma counter for clinical use.
862.2485 ..	Electrophoresis apparatus for clinical use.
862.2720 ..	Plasma oncometer for clinical use.
862.2800 ..	Refractometer for clinical use.
862.2920 ..	Plasma viscometer for clinical use.
864.2280 ..	Cultured animal and human cells.
866.5570 ..	Lactoferrin immunological test system.
868.5620 ..	Breathing mouthpiece.
868.5675 ..	Rebreathing device.
868.5700 ..	Nonpowered oxygen tent.
872.3740 ..	Retentive and splinting pin.
872.3810 ..	Root canal post.
872.6100 ..	Anesthetic warmer.
886.5850 ..	Sunglasses (nonprescription).

FDA will address these devices in a future issue of the Federal Register.

FDA received no adverse comments on 148 of the devices that it proposed be exempted from the requirement of premarket notification. For these 148 devices, FDA has concluded that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. Thus, FDA is finalizing the exemptions for these 148 devices from premarket notification procedures.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule reduces a regulatory burden by exempting manufacturers of devices subject to the final rule from the requirements of premarket notification, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Parts 868, 870, 872, 874, 876, 878, 880, 882, 888, and 890

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 864.5350 is amended by revising paragraph (b) to read as follows:

§ 864.5350 Microsedimentation centrifuge.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

3. Section 864.7660 is amended by revising paragraph (b) to read as follows:

§ 864.7660 Leukocyte alkaline phosphatase test.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

4. Section 864.7675 is amended by revising paragraph (b) to read as follows:

§ 864.7675 Leukocyte peroxidase test.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

5. Section 864.7900 is amended by revising paragraph (b) to read as follows:

§ 864.7900 Thromboplastin generation test.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

6. Section 864.8500 is amended by revising paragraph (b) to read as follows:

§ 864.8500 Lymphocyte separation medium.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

7. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

8. Section 866.5170 is amended by revising paragraph (b) to read as follows:

§ 866.5170 Breast milk immunological test system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

9. Section 866.5220 is amended by revising paragraph (b) to read as follows:

§ 866.5220 Cohn fraction II immunological test system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

10. Section 866.5230 is amended by revising paragraph (b) to read as follows:

§ 866.5230 Colostrum immunological test system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

11. Section 866.5360 is amended by revising paragraph (b) to read as follows:

§ 866.5360 Cohn fraction IV immunological test system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

12. Section 866.5370 is amended by revising paragraph (b) to read as follows:

§ 866.5370 Cohn fraction V immunological test system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

13. Section 866.5540 is amended by revising paragraph (b) to read as follows:

§ 866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

14. Section 866.5700 is amended by revising paragraph (b) to read as follows:

§ 866.5700 Whole human plasma or serum immunological test system.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 868—ANESTHESIOLOGY DEVICES

15. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

16. Section 868.5340 is amended by revising paragraph (b) to read as follows:

§ 868.5340 Nasal oxygen cannula.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

17. Section 868.5350 is amended by revising paragraph (b) to read as follows:

§ 868.5350 Nasal oxygen catheter.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 870—CARDIOVASCULAR DEVICES

18. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

19. Section 870.1875 is amended by revising paragraph (a)(2) to read as follows:

§ 870.1875 Stethoscope.

(a) . . .

(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 872—DENTAL DEVICES

20. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

21. Section 872.1500 is amended by revising paragraph (b) to read as follows:

§ 872.1500 Gingival fluid measurer.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

22. Section 872.1820 is amended by revising paragraph (b) to read as follows:

§ 872.1820 Dental X-ray exposure alignment device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

23. Section 872.3100 is amended by revising paragraph (b) to read as follows:

§ 872.3100 Dental amalgamator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

24. Section 872.3130 is amended by revising paragraph (b) to read as follows:

§ 872.3130 Preformed anchor.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

25. Section 872.3165 is amended by revising paragraph (b) to read as follows:

§ 872.3165 Precision attachment.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

26. Section 872.3240 is amended by revising paragraph (b) to read as follows:

§ 872.3240 Dental bur.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

27. Section 872.3285 is amended by revising paragraph (b) to read as follows:

§ 872.3285 Preformed clasp.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

28. Section 872.3330 is amended by revising paragraph (b) to read as follows:

§ 872.3330 Preformed crown.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

29. Section 872.3350 is amended by revising paragraph (b) to read as follows:

§ 872.3350 Gold or stainless steel cusp.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

30. Section 872.3360 is amended by revising paragraph (b) to read as follows:

§ 872.3360 Preformed cusp.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

31. Section 872.3410 is amended by revising paragraph (b) to read as follows:

§ 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

32. Section 872.3450 is amended by revising paragraph (b) to read as follows:

§ 872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

33. Section 872.3490 is amended by revising paragraph (b) to read as follows:

§ 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

34. Section 872.3520 is amended by revising paragraph (b) to read as follows:

§ 872.3520 OTC denture cleanser.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

35. Section 872.3530 is amended by revising paragraph (b) to read as follows:

§ 872.3530 Mechanical denture cleaner.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

36. Section 872.3580 is amended by revising paragraph (b) to read as follows:

§ 872.3580 Preformed gold denture tooth.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

37. Section 872.3670 is amended by revising paragraph (b) to read as follows:

§ 872.3670 Resin impression tray material.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

38. Section 872.3900 is amended by revising paragraph (b) to read as follows:

§ 872.3900 Posterior artificial tooth with a metal insert.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

39. Section 872.3910 is amended by revising paragraph (b) to read as follows:

§ 872.3910 Backing and facing for an artificial tooth.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

40. Section 872.4130 is amended by revising paragraph (b) to read as follows:

§ 872.4130 Intraoral dental drill.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

41. Section 872.4535 is amended by revising paragraph (b) to read as follows:

§ 872.4535 Dental diamond instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

42. Section 872.4620 is amended by revising paragraph (b) to read as follows:

§ 872.4620 Fiber optic dental light.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

43. Section 872.4730 is amended by revising paragraph (b) to read as follows:

§ 872.4730 Dental injecting needle.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

44. Section 872.5410 is amended by revising paragraph (b) to read as follows:

§ 872.5410 Orthodontic appliance and accessories.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

45. Section 872.5525 is amended by revising paragraph (b) to read as follows:

§ 872.5525 Preformed tooth positioner.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

46. Section 872.5550 is amended by revising paragraph (b)(1) to read as follows:

§ 872.5550 Teething ring.

(b)(1) *Classification.* Class I if the teething ring does not contain a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

47. Section 872.6030 is amended by revising paragraph (b) to read as follows:

§ 872.6030 Oral cavity abrasive polishing agent.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

48. Section 872.6140 is amended by revising paragraph (b) to read as follows:

§ 872.6140 Articulation paper.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

49. Section 872.6250 is amended by revising paragraph (b) to read as follows:

§ 872.6250 Dental chair and accessories.

(b) *Classification.* Class I. The dental chair without the operative unit device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

50. Section 872.6300 is amended by revising paragraph (b) to read as follows:

§ 872.6300 Rubber dam and accessories.

(b) *Classification.* Class I. The accessories to the device, i.e., rubber dam clamp, rubber dam frame and forceps for a rubber dam clamp, are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

51. Section 872.6475 is amended by revising paragraph (b) to read as follows:

§ 872.6475 Heat source for bleaching teeth.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

52. Section 872.6510 is amended by revising paragraph (b) to read as follows:

§ 872.6510 Oral irrigation unit.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

53. Section 872.6640 is amended by revising paragraph (b) to read as follows:

§ 872.6640 Dental operative unit and accessories.

(b) *Classification.* Class I. The accessories tray to the dental operative unit is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

54. Section 872.6865 is amended by revising paragraph (b) to read as follows:

§ 872.6865 Powered toothbrush.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

55. Section 872.6890 is amended by revising paragraph (b) to read as follows:

§ 872.6890 Intraoral dental wax.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to

general requirements concerning records, and § 820.198, with respect to complaint files.

PART 874—EAR, NOSE, AND THROAT DEVICES

56. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

57. Section 874.3375 is amended by revising paragraph (b) to read as follows:

§ 874.3375 Battery-powered artificial larynx.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

58. Section 874.4750 is amended by revising paragraph (b) to read as follows:

§ 874.4750 Laryngostroboscope.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

59. Section 874.5220 is amended by revising paragraph (b) to read as follows:

§ 874.5220 Ear, nose, and throat drug administration device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

60. Section 874.5800 is amended by revising paragraph (b) to read as follows:

§ 874.5800 External nasal splint.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

**PART 876—GASTROENTEROLOGY-
UROLOGY DEVICES**

61. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

62. Section 876.5970 is amended by revising paragraph (b) to read as follows:

§ 876.5970 Hernia support.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

**PART 878—GENERAL AND PLASTIC
SURGERY DEVICES**

63. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

64. Section 878.1800 is amended by revising paragraph (b) to read as follows:

§ 878.1800 Speculum and accessories.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

65. Section 878.3750 is amended by revising paragraph (b) to read as follows:

§ 878.3750 External prosthesis adhesive.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

66. Section 878.3800 is amended by revising paragraph (b) to read as follows:

§ 878.3800 External aesthetic restoration prosthesis.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements

concerning records, and § 820.198, with respect to complaint files.

67. Section 878.3900 is amended by revising paragraph (b) to read as follows:

§ 878.3900 Inflatable extremity splint.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

68. Section 878.4100 is amended by revising paragraph (b) to read as follows:

§ 878.4100 Organ bag.

(b) *Classification*. Class I. The intestinal organ bag device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

69. Section 878.4380 is amended by revising paragraph (b) to read as follows:

§ 878.4380 Drape adhesive.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

70. Section 878.4440 is amended by revising paragraph (b) to read as follows:

§ 878.4440 Eye pad.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

71. Section 878.4470 is amended by revising paragraph (b) to read as follows:

§ 878.4470 Surgeon's gloving cream.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

72. Section 878.4635 is amended by revising paragraph (b) to read as follows:

§ 878.4635 Ultraviolet lamp for tanning.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

73. Section 878.4660 is amended by revising paragraph (b) to read as follows:

§ 878.4660 Skin marker.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

74. Section 878.4700 is amended by revising paragraph (b) to read as follows:

§ 878.4700 Surgical microscope and accessories.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

75. Section 878.4730 is amended by revising paragraph (b) to read as follows:

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

76. Section 878.4800 is amended by revising paragraph (b) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

77. Section 878.4930 is amended by revising paragraph (b) to read as follows:

§ 878.4930 Suture retention device.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

78. Section 878.4950 is amended by revising paragraph (b) to read as follows:

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

79. Section 878.5900 is amended by revising paragraph (b) to read as follows:

§ 878.5900 Nonpneumatic tourniquet.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

**PART 880—GENERAL HOSPITAL AND
PERSONAL USE DEVICES**

80. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

81. Section 880.2400 is amended by revising paragraph (b) to read as follows:

§ 880.2400 Bed-patient monitor.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

82. Section 880.2720 is amended by revising paragraph (b)(1) to read as follows:

§ 880.2720 Patient scale.

(b) *Classification.* (1) Class I for a mechanical or battery powered patient scale. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

83. Section 880.5180 is amended by revising paragraph (b) to read as follows:

§ 880.5180 Burn sheet.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

84. Section 880.5210 is amended by revising paragraph (b) to read as follows:

§ 880.5210 Intravascular catheter securement device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

85. Section 880.5240 is amended by revising paragraph (b) to read as follows:

§ 880.5240 Medical adhesive tape and adhesive bandage.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

86. Section 880.5630 is amended by revising paragraph (b) to read as follows:

§ 880.5630 Nipple shield.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

87. Section 880.5740 is amended by revising paragraph (b) to read as follows:

§ 880.5740 Suction snakebite kit.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

88. Section 880.5780 is amended by revising paragraph (b)(2) to read as follows:

§ 880.5780 Medical support stocking.

(b) . . .

(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

89. Section 880.5950 is amended by revising paragraph (b) to read as follows:

§ 880.5950 Umbilical occlusion device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

90. Section 880.6060 is amended by revising paragraph (b) to read as follows:

§ 880.6060 Medical disposable bedding.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

91. Section 880.6150 is amended by revising paragraph (b) to read as follows:

§ 880.6150 Ultrasonic cleaner for medical instruments.

(b) *Classification.* Class I. The device, including any solutions intended for use with the device for cleaning and sanitizing the instruments, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

92. Section 880.6190 is amended by revising paragraph (b) to read as follows:

§ 880.6190 Mattress cover for medical purposes.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

93. Section 880.6900 is amended by revising paragraph (b) to read as follows:

§ 880.6900 Hand-carried stretcher.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 882—NEUROLOGICAL DEVICES

94. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

95. Section 882.1430 is amended by revising paragraph (b) to read as follows:

§ 882.1430 Electroencephalograph test signal generator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

96. Section 882.1700 is amended by revising paragraph (b) to read as follows:

§ 882.1700 Percussor.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

97. Section 882.1925 is amended by revising paragraph (b) to read as follows:

§ 882.1925 Ultrasonic scanner calibration test block.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

98. Section 882.4030 is amended by revising paragraph (b) to read as follows:

§ 882.4030 Skull plate anvil.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

99. Section 882.4125 is amended by revising paragraph (b) to read as follows:

§ 882.4125 Neurosurgical chair.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

100. Section 882.4190 is amended by revising paragraph (b) to read as follows:

§ 882.4190 Clip forming/cutting instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

101. Section 882.4200 is amended by revising paragraph (b) to read as follows:

§ 882.4200 Clip removal instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

102. Section 882.4215 is amended by revising paragraph (b) to read as follows:

§ 882.4215 Clip rack.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

103. Section 882.4440 is amended by revising paragraph (b) to read as follows:

§ 882.4440 Neurosurgical headrest.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

104. Section 882.4500 is amended by revising paragraph (b) to read as follows:

§ 882.4500 Cranioplasty material forming instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

105. Section 882.4525 is amended by revising paragraph (b) to read as follows:

§ 882.4525 Microsurgical instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

106. Section 882.4535 is amended by revising paragraph (b) to read as follows:

§ 882.4535 Nonpowered neurosurgical instrument.

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

107. Section 882.4600 is amended by revising paragraph (b) to read as follows:

§ 882.4600 Leukotome.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

108. Section 882.4900 is amended by revising paragraph (b) to read as follows:

§ 882.4900 Skullplate screwdriver.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 886—OPHTHALMIC DEVICES

109. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

110. Section 886.1040 is amended by revising paragraph (b) to read as follows:

§ 886.1040 Ocular esthesiometer.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

111. Section 886.1050 is amended by revising paragraph (b) to read as follows:

§ 886.1050 Adaptometer (biophotometer).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

112. Section 886.1070 is amended by revising paragraph (b) to read as follows:

§ 886.1070 Anomaloscope.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

113. Section 886.1090 is amended by revising paragraph (b) to read as follows:

§ 886.1090 Haidinger brush.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

114. Section 886.1140 is amended by revising paragraph (b) to read as follows:

§ 886.1140 Ophthalmic chair.

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

115. Section 886.1160 is amended by revising paragraph (b) to read as follows:

§ 886.1160 Color vision plate illuminator.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

116. Section 886.1250 is amended by revising paragraph (b) to read as follows:

§ 886.1250 Euthyscope.

(b) *Classification.* Class I for the battery powered device. The battery powered device is exempt from premarket notification procedures in subpart E of part 807 of this chapter. Class II for the AC-powered device.

117. Section 886.1290 is amended by revising paragraph (b) to read as follows:

§ 886.1290 Fixation device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

118. Section 886.1340 is amended by revising paragraph (b) to read as follows:

§ 886.1340 Haploscope.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

119. Section 886.1350 is amended by revising paragraph (b) to read as follows:

§ 886.1350 Keratoscope.

(b) *Classification.* Class I. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device does not include computer software in the unit. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning

records, and § 820.198, with respect to complaint files.

120. Section 886.1425 is amended by revising paragraph (b) to read as follows:

§ 886.1425 Lens measuring instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

121. Section 886.1430 is amended by revising paragraph (b) to read as follows:

§ 886.1430 Ophthalmic contact lens radius measuring device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

122. Section 886.1435 is amended by revising paragraph (b) to read as follows:

§ 886.1435 Maxwell spot.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

123. Section 886.1450 is amended by revising paragraph (b) to read as follows:

§ 886.1450 Corneal radius measuring device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device does not include computer software in the unit or topographers.

124. Section 886.1660 is amended by revising paragraph (b) to read as follows:

§ 886.1660 Gonioscopic prism.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

125. Section 886.1680 is amended by revising paragraph (b) to read as follows:

§ 886.1680 Ophthalmic projector.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

126. Section 886.1690 is amended by revising paragraph (b) to read as follows:

§ 886.1690 Pupillograph.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

127. Section 886.1700 is amended by revising paragraph (b) to read as follows:

§ 886.1700 Pupilometer.

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

128. Section 886.1810 is amended by revising paragraph (b) to read as follows:

§ 886.1810 Tangent screen (campimeter).

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

129. Section 886.1860 is amended by revising paragraph (b) to read as follows:

§ 886.1860 Ophthalmic instrument stand.

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

130. Section 886.1870 is amended by revising paragraph (b) to read as follows:

§ 886.1870 Stereoscope.

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

131. Section 886.1910 is amended by revising paragraph (b) to read as follows:

§ 886.1910 Spectacle dissociation test system.

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

132. Section 886.1945 is amended by revising paragraph (b) to read as follows:

§ 886.1945 Transilluminator.

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

133. Section 886.4250 is amended by revising paragraph (b) to read as follows:

§ 886.4250 Ophthalmic electrolysis unit.

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

134. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device meets the ANSI standard on optic radiation limits.

135. Section 886.4360 is amended by revising paragraph (b) to read as follows:

§ 886.4360 Ocular surgery irrigation device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

136. Section 886.4570 is amended by revising paragraph (b) to read as follows:

§ 886.4570 Ophthalmic surgical marker.

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

137. Section 886.4750 is amended by revising paragraph (b) to read as follows:

§ 886.4750 Ophthalmic eye shield.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

138. Section 886.4855 is amended by revising paragraph (b) to read as follows:

§ 886.4855 Ophthalmic instrument table.

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

139. Section 886.5820 is amended by revising paragraph (b) to read as follows:

§ 886.5820 Closed-circuit television reading system.

(b) *Classification.* Class I. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

140. Section 886.5840 is amended by revising paragraph (b) to read as follows:

§ 886.5840 Magnifying spectacles.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

141. Section 886.5842 is amended by revising paragraph (b) to read as follows:

§ 886.5842 Spectacle frame.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

142. Section 886.5844 is amended by revising paragraph (b) to read as follows:

§ 886.5844 Prescription spectacle lens.

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

143. Section 886.5900 is amended by revising paragraph (b) to read as follows:

§ 886.5900 Electronic vision aid.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

144. Section 886.5915 is amended by revising paragraph (b) to read as follows:

§ 886.5915 Optical vision aid.

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 888—ORTHOPEDIC DEVICES

145. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

146. Section 888.4200 is amended by revising paragraph (b) to read as follows:

§ 888.4200 Cement dispenser.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

147. Section 888.4210 is amended by revising paragraph (b) to read as follows:

§ 888.4210 Cement mixer for clinical use.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

148. Section 888.4230 is amended by revising paragraph (b) to read as follows:

§ 888.4230 Cement ventilation tube.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

149. Section 888.4540 is amended by revising paragraph (b) to read as follows:

§ 888.4540 Orthopedic manual surgical instrument.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

150. Section 888.5940 is amended by revising paragraph (b) to read as follows:

§ 888.5940 Cast component.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 890—PHYSICAL MEDICINE DEVICES

151. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

152. Section 890.1175 is amended by revising paragraph (b) to read as follows:

§ 890.1175 Electrode cable.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The devices are also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

153. Section 890.3100 is amended by revising paragraph (b) to read as follows:

§ 890.3100 Mechanical chair.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

154. Section 890.3750 is amended by revising paragraph (b) to read as follows:

§ 890.3750 Mechanical table.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

155. Section 890.3920 is amended by revising paragraph (b) to read as follows:

§ 890.3920 Wheelchair component.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

156. Section 890.3940 is amended by revising paragraph (b) to read as follows:

§ 890.3940 Wheelchair platform scale.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

157. Section 890.5765 is amended by revising paragraph (b) to read as follows:

§ 890.5765 Pressure-applying device.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 892—RADIOLOGY DEVICES

158. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

159. Section 892.1130 is amended by revising paragraph (b) to read as follows:

§ 892.1130 Nuclear whole body counter.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

160. Section 892.1350 is amended by revising paragraph (b) to read as follows:

§ 892.1350 Nuclear scanning bed.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device is labeled with weight limit, is used with planar scanning only, and is not for diagnostic X-ray use.

161. Section 892.1640 is amended by revising paragraph (b) to read as follows:

§ 892.1640 Radiographic film marking system.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

162. Section 892.5740 is amended by revising paragraph (b) to read as follows:

§ 892.5740 Radionuclide teletherapy source.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: November 30, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

(FR Doc. 94-30025 Filed 12-2-94; 12:01 pm)

BILLING CODE 4160-01-P

DEPARTMENT OF JUSTICE

Office of Justice Programs

28 CFR Part 91

[OJP No. 1011]

RIN 1121-AA25

Violent Offender Incarceration and Truth In Sentencing Incentive Grant Program

AGENCY: Department of Justice, Office of Justice Programs (OJP).

ACTION: Interim final rule.

SUMMARY: This interim rule implements and requests comments regarding the Violent Offender Incarceration and Truth in Sentencing Incentive Grant Program, Subtitle A of Title II of the Violent Crime Control and Law Enforcement Act of 1994.

The Violent Offender Incarceration and Truth in Sentencing Grant Program will provide grants to states, and states organized in multi-state compacts, for assistance to correctional systems. These regulations are being issued in accordance with the mandate in Subtitle A of Title II that rules and regulations regarding the uses of grant funds under this program be issued. While this rule discusses the implementation of the overall Subtitle A program, fiscal year 1995 funds have only been appropriated for the construction-related costs of correctional boot camps.

DATES: Interim rule effective on December 7, 1994; comments must be received March 7, 1995.

ADDRESSES: Comments may be sent to Marlene Beckman at the Office of Justice Programs, 633 Indiana Avenue, 13th Floor, NW, Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: The Department of Justice Response Center at 1-800-421-6770 or (202) 307-1480.

SUPPLEMENTARY INFORMATION: Federal funding is authorized under Subtitle A

of Title II of the Violent Crime Control and Law Enforcement Act of 1994 (Subtitle A), Public Law 103-322, for grants to states, and states organized in multi-state compacts, for assistance to adult and juvenile correctional systems. The program recognizes that states and local jurisdictions have experienced substantial increases in jail, prison and juvenile confinement populations in recent years, resulting in escalating costs and serious difficulties in managing overcapacity correctional populations. Because of these constraints, correctional systems have often been unable to implement new programs, develop alternative confinement strategies, or open new facilities. This program seeks to provide funds to address the immediate needs of correctional facilities and programs.

In particular, the program emphasizes the need to make available both conventional jail and prison space for the confinement of violent offenders and to ensure that violent offenders remain incarcerated for substantial periods of time through the implementation of truth in sentencing laws. Accordingly, Subtitle A directs the Attorney General to award grants to construct, develop, expand, modify, operate, or improve correctional facilities, including boot camp facilities and other alternative correctional facilities that will free secure prison space for the confinement of violent offenders.

Fifty percent of the total amount of funds appropriated each year will be allocated for Truth in Sentencing Incentive Grants and the other 50 percent will be allocated for Violent Offender Incarceration Grants, 85 percent of which is to be distributed by specified formula with the remaining 15 percent available for discretionary grant awards.

The formula amount available to carry out the grant programs for any fiscal year will be allocated to each eligible state based on Part 1 violent crime data reported to the Federal Bureau of Investigation for use in the Uniform Crime Reports (UCR). If such data is unavailable, applicants may also utilize figures as reported in publications by the Bureau of Justice Statistics (BJS). (See, e.g., "Census of State and Local Correctional Facilities, 1990.")

The statute contemplates the availability of \$7.9 billion in funding over six years, beginning with \$175 million authorized in fiscal year 1995. It is important to note, however, that Congress appropriated only \$24.5 million for Subtitle A programs for fiscal year 1995. Moreover, the Appropriations Act limits these funds to