



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2012-N-1239]

Dental Devices; Reclassification of Temporary Mandibular Condyle Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed order to reclassify temporary mandibular condyle prosthesis, a preamendments class III device, into class II (special controls), and rename the device “temporary mandibular condyle reconstruction plate.” FDA is also issuing the draft special controls guideline, “Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate,” which sets forth the special controls that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: Submit either electronic or written comments on this proposed order or on the draft guideline by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section XIII of this document for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-1239, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

### Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No.

FDA-2012-N-1239. All comments received may be posted without change to

<http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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## SUPPLEMENTARY INFORMATION:

### I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), the Medical Devices Technical Corrections Act (Public Law 108-214), the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon “new information.” FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA to reclassify a preamendments device. The term “new information,” as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos Co. v. United States Department of Health, Education, and Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see Bell, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F.Supp. 382, 388-391 (D.D.C. 1991)), or in light of changes in “medical science” (Upjohn, 422 F.2d at 951). Whether data before the Agency are old or new data, the “new information” to support reclassification under section 513(e) must be “valid scientific evidence,” as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Association v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. FDA has held a meeting of a device classification panel described

in section 513(b) of the FD&C Act with respect to temporary mandibular condyle prosthesis, and therefore, has met this requirement under section 513(e)(1) of the FD&C Act. As explained further in section II of this document, a meeting of a device classification panel described in section 513(b) of the FD&C Act took place in 1997 to discuss whether temporary mandibular condyle prosthesis should be reclassified or remain in class III, and the panel recommended that the device be reclassified into class II because there was sufficient information to establish special controls. FDA is not aware of new information since the 1997 panel that would provide a basis for a different recommendation or findings.

FDAMA added section 510(m) to the FD&C Act. Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

## II. Regulatory History of the Device

In 1994, FDA issued a final rule that classified all mandibular condyle prostheses into class III, based on the recommendation of a Dental Products Panel (the Panel) meeting on February 11, 1993 (59 FR 65475; December 20, 1994). In response to a petition dated April 30, 1996 (FDA-1996-P-0253), FDA considered a distinction between temporary and permanent mandibular condyle prostheses and held a February 12, 1997 meeting of the Panel. The Panel recommended that mandibular condyle prostheses indicated for temporary reconstruction of the mandibular condyle in tumor resection patients be reclassified from class III to class II with special controls, include labeling for temporary use not to exceed 2 years, and have patient registries. Based on its review of the data and information contained in the April 30, 1996, petition, the Panel believed that special controls, in addition to general controls, were necessary

to provide a reasonable assurance of safety and effectiveness of these devices in patients who have undergone resective procedures to remove malignant or benign tumors, requiring the removal of the mandibular condyle and mandibular bone. On December 30, 1998, FDA issued a final rule calling for PMAs under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) for permanent mandibular condyle prostheses, and simultaneously announced its intention to reclassify, in accordance with the Panel's recommendations, mandibular condyle prosthesis for temporary reconstruction following surgical ablation of malignant and benign tumors (63 FR 71743).

In 2009, FDA published an order for the submission of information on mandibular condyle prostheses indicated for temporary reconstruction (74 FR 16214; April 9, 2009). In response to that order, FDA received information from several device manufacturers who recommended that these devices be reclassified to class II. The manufacturers stated that the safety and effectiveness of these devices may be reasonably assured by bench testing, biocompatibility testing, sterility testing, expiration date testing, labeling, and performance standards.

On the basis of its review and the recommendations from the Panel and industry, FDA now believes that the use of temporary mandibular condyle prostheses for patients who have undergone any resective surgical procedure requiring removal of the mandibular condyle and mandibular bone does not present a potential unreasonable risk of illness and injury, and that special controls, in addition to general controls, are necessary to provide reasonable assurance of the safety and effectiveness of the device. Although the Panel recommended that class II was appropriate for plates indicated in tumor resection cases only, FDA believes that the special controls proposed in this document are appropriate to provide reasonable assurance of safety and

effectiveness for temporary reconstruction of the mandibular condyle in patients who have undergone any resective surgical procedures requiring removal of the mandibular condyle and mandibular bone.

### III. Device Description

A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.

FDA is proposing this order to create a new classification for the temporary mandibular condyle prosthesis and rename it the temporary mandibular condyle reconstruction plate (TMCRP) to distinguish it from permanent mandibular condyle prosthesis. TMCRP devices will be identified as:

A TMCRP is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.

The new classification will be placed under 21 CFR part 872, subpart E--Surgical Devices, as a TMCRP is not intended to permanently replace the function of the mandibular condyle.

### IV. Proposed Reclassification

FDA is proposing that temporary mandibular condyle prosthesis be reclassified from class III to class II with a special controls guideline. FDA is also proposing to create a separate classification for these devices, to rename them temporary mandibular condyle reconstruction plate, and place them under 21 CFR part 872, subpart E--Surgical Devices, to differentiate them



from permanent mandibular condyle prostheses and clarify that these devices are intended as temporary devices and not permanent replacements of the mandibular condyle. FDA believes that these devices can be utilized to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone.

FDA has considered TMCRPs in accordance with the reserved criteria and determined that these devices require premarket notification. The Agency does not intend to exempt this proposed class II device from premarket notification (section 510(k) of the FD&C Act) submission as provided for under section 510(m) of the FD&C Act.

#### V. Risks to Health

After considering the information from the reports and recommendations of the Panel for the classification of these devices along with information submitted in response to the section 515(i) order and any additional information that FDA has at its disposal, FDA has identified and evaluated the risks to health associated with the use of TMCRPs. The Panel had identified these risks to health for all mandibular condyle prostheses in a February 11, 1993, meeting; FDA believes that the risks listed in this document are applicable to TMCRPs, a subset of mandibular condyle prostheses, and that these concerns are still relevant today.

- Loosening, migration, or exposure. TMCRP screws or plates may loosen if not placed properly. A loose plate can also lead to migration or exposure of the plate or screws through the skin.
- Mechanical wear of the plate or screws and foreign body reaction. Some materials used in the construction of a TMCRP may wear and release particles that may result in a

foreign body reaction.

- Structural/mechanical failure. A TMCRP may loosen, bend, or fracture and result in a structural or mechanical failure of the plate if not placed properly or used longer than intended.
- Migration or thermal injury from magnetic resonance scans. A TMCRP is composed of metals. Certain metallic materials that may be used for a TMCRP can be induced to displace or heat up in the presence of a magnetic field, such as is found in magnetic resonance scans.
- Corrosion. A TMCRP is composed of metals. Some materials to be used for a TMCRP may corrode, which can lead to failure and adverse tissue reaction.
- Adverse reaction to a TMCRP. Placement of a TMCRP may result in an adverse reaction in certain individuals who may be hypersensitive or allergic to the materials of composition of the TMCRP.
- Infection. Placement of a TMCRP may result in a postoperative infection due to the surgical procedure or if the plate or screws have not been sterilized appropriately.
- Degenerative changes to the glenoid fossa surfaces. A TMCRP may cause degeneration of the opposing bone, which is an inherent risk of a metal-on-bone joint.
- Malocclusion, changes in mastication and contralateral joint. A TMCRP may cause an uneven bite, resulting in malocclusion and potential changes in the contralateral joint, which is a unique risk of a bilateral joint.
- User error. A TMCRP may be misused if placed incorrectly or if inappropriately used as a permanent prosthesis rather than a temporary reconstruction plate.
- Transient or chronic pain and facial nerve paresis. Placement of a TMCRP may cause

transient or chronic pain or nerve paresis associated with changes in jaw structure and function as a result of the surgical procedure.

#### VI. Summary of Reasons for Reclassification

FDA believes that TMCRPs should be reclassified into class II because special controls, in addition to general controls, are necessary to provide reasonable assurance of the safety and effectiveness of the devices. In addition, there is now sufficient information sufficient to establish special controls to provide such assurance.

#### VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and 21 CFR 860.130, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The new information includes the history of use of the device and the relative absence of adverse events reports despite the longstanding use of these devices, as discussed in the recommendations for reclassification from the device industry (available in docket FDA-2009-M-0101 at <http://www.regulations.gov>) and the February 12, 1997, Panel. The classification recommendations from the device industry recommend that FDA reclassify these devices to class II based on their history of use without evidence of serious adverse events and the ability of preclinical data to provide predictive performance information. These companies cite their own history of use, their own preclinical testing, and relevant peer-reviewed literature that provide evidence that TMCRPs are effective for temporary reconstruction of the mandible and not associated with complications. (Ref. 1) The Panel also recommended reclassification to class II for these devices and believed that

special controls, in addition to general controls, would provide a reasonable assurance of safety and effectiveness for these devices. (Ref. 2) FDA believes that this information constitutes sufficient evidence to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V of this document, which are known surgical risks, and that these special controls in addition to the general controls will provide a reasonable assurance of safety and effectiveness for TMCRPs. Although the Panel only recommended that class II was appropriate for plates indicated in tumor resection cases only, FDA believes that the proposed special controls are appropriate to provide reasonable assurance of safety and effectiveness for temporary reconstruction of the mandibular condyle in patients who have undergone any resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. Other clinical instances that may result in mandibular resection include certain traumas, osteoradionecrosis, bisphosphonate-induced osteonecrosis, and osteomyelitis. FDA believes that the risks of using TMCRPs in these instances are the same as the risks in tumor resection cases, and therefore the identified special controls can provide a reasonable assurance of safety and effectiveness for TMCRPs in the following indications: when used to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone.

#### VIII. Proposed Special Controls--Related Document

FDA believes that the measures set forth in the special controls guideline “Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate” are necessary, in addition to general controls, to mitigate the risks to health described in section V in this document. As seen in the following table, the special controls set forth in the guideline for

this device address each of the identified risks.

Table 1. -- TMCRP Risks and Mitigation Measures

| Identified Risk  | Mitigation Measure   |
|--|--|
| Loosening, migration or exposure                                 | Section 5 – Materials and Performance Data<br>Section 8 – Labeling |
| Mechanical wear of the plate or screws and foreign body reaction | Section 5 – Materials and Performance Data                         |
| Structural/mechanical failure                                    | Section 5 – Materials and Performance Data                         |
| Migration or thermal injury from magnetic resonance scans        | Section 5 – Materials and Performance Data                         |
| Corrosion  | Section 5 – Materials and Performance Data                         |
| Adverse reaction to TMCRP  | Section 6 – Biocompatibility                                       |
| Infection  | Section 7 – Sterilization  |
| Degenerative changes to glenoid fossa surfaces                   | Section 8 – Labeling   |
| Malocclusion, changes in mastication, and contralateral joint    | Section 8 – Labeling   |
| User error   | Section 8 – Labeling   |
| Transient or chronic pain and facial nerve paresis               | Section 8 – Labeling   |

If this proposed order is finalized, TMCRLs will be reclassified into Class II. As discussed below, the reclassification will be codified in 21 CFR 872.4770. Firms submitting a 510(k) for a TMCRL will need either to (1) comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Adherence to the criteria in the guideline, when finalized, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of the devices.

#### IX. Electronic Access to the Special Controls Guideline

Persons interested in obtaining a copy of the draft guideline may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidelines and guidance documents is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default>

[t.htm](http://www.regulations.gov). The guideline is also available at <http://www.regulations.gov>.

To receive “Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate,” you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1799 to identify the guidance you are requesting.

## X. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

## XI. Paperwork Reduction Act of 1995

This proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

## XII. Clarifications to Special Controls Guidelines

This special controls guideline reflects changes the Agency is making to clarify its position on the binding nature of special controls. The changes include referring to the document as a “guideline,” as that term is used in section 513(a) of the FD&C Act, which the Secretary has developed and disseminated to provide a reasonable assurance of safety and effectiveness for

class II devices, and not a “guidance,” as that term is used in 21 CFR 10.115. The guideline also clarifies that firms will need either to (1) comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency’s satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Finally, the guideline uses mandatory language to emphasize that firms must comply with special controls to legally market their class II devices. These revisions do not represent a change in FDA’s position about the binding effect of special controls, but rather are intended to address any possible confusion or misunderstanding.

### XIII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective on the date of its publication in the Federal Register or at a later date if stated in the final order.

### XIV. Comments

Interested persons may submit either electronic comments regarding this document or the associated Special Controls guideline to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### XV. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue

final orders rather than regulations, FDASIA also provides for FDA to revoke previously promulgated regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, pursuant to section 513(e)(1)(A)(i), as amended by FDASIA, in this proposed order, we are proposing to revoke the requirements in 21 CFR 872.3960 related to the classification of TMCRPs as Class III devices and to codify the reclassification of TMCRPs into Class II.

## XVI. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carlson, E.R., Disarticulation Resections of the Mandible: A Prospective Review of 16 Cases. Journal of Oral and Maxillofacial Surgery, vol. 60, pp. 176-181, 2002.
2. Food and Drug Administration, Dental Products Advisory Panel Meeting Transcript, February 12, 1997;  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=168>.

### List of Subjects in 21 CFR Part 872

Medical devices.



Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

#### PART 872--DENTAL DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

\* \* \* \* \*

(c) Date PMA or notice of completion of PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

3. Section 872.4770 is added to subpart E to read as follows:

§ 872.4770 Temporary mandibular condyle reconstruction plate.

(a) Identification. A temporary mandibular condyle reconstruction plate is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.

(b) Classification. Class II (special controls). The special controls is FDA's guideline, "Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate."

See § 872.1(e) for the availability of this guidance document.

Dated: February 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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