4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2013-N-0069]

Medical Devices; Ophthalmic Devices; Classification of the Eyelid Weight

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the eyelid weight into class II (special controls). The Agency is exempting the external eyelid weight from premarket notification, but continuing to require premarket notification for implantable eyelid weights in order to provide a reasonable assurance of safety and effectiveness of the device. Both external and implantable eyelid weight devices are subject to special controls. The eyelid weight may be adhered to the outer skin of the upper eyelid (external eyelid weight) or implanted into the upper eyelid (implantable eyelid weight), and is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

DATES: Effective Date: [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Compliance Dates: Premarket notification submissions (510(k)s) for eyelid weights filed on or after the effective date of this rule are expected to comply with the requirement of special controls at the time that the 510(k) is submitted.

Premarket notification submissions (510(k)s) for eyelid weights filed before the effective date of this rule, but not yet cleared for marketing, are expected to comply with the requirement of special controls prior to receiving marketing clearance.

External eyelid weights exempt from premarket notification under this rule and not currently marketed are expected to comply with the requirement of special controls prior to introducing devices into interstate commerce.

Eyelid weights (both implantable and external) legally marketed before the effective date of this rule are expected to comply with the requirement of special controls by April 21, 2015. See section V of this document, "Compliance Dates," for further information.

FOR FURTHER INFORMATION CONTACT: Tina Kiang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2414, Silver Spring, MD 20993-0002, 301-796-6860, Tina.Kiang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 et seq.), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L.105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug Administration Safety and Innovation Act (Pub. L. 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, depending on 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 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as "preamendments devices." FDA classifies these devices after the Agency takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as "postamendments devices." These devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under 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 of the regulations (21 CFR part 807).

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval

application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 510(m) of the FD&C Act (21 U.S.C. 360(m)) 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 the Federal Register of February 8, 2013 (78 FR 9349), FDA proposed to classify eyelid weight devices intended for the gravity-assisted treatment of lagophthalmos (incomplete eyelid closure) into class II (special controls) and proposed special controls for these devices. FDA also proposed to exempt the devices from premarket notification requirements if the device is an external eyelid weight. FDA invited interested persons to comment on the proposed regulation by May 9, 2013. FDA received three comments on the proposed rule.

III. Summary of the Final Rule

In accordance with 21 CFR 860.84(g)(2), FDA is classifying eyelid weights into class II (special controls). FDA is codifying the classification of eyelid weights by adding § 886.5700.

A. External Eyelid Weights

Under section 510(m) of the FD&C Act, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of external eyelid weights, and the Agency is exempting these devices from premarket notification requirements. The Agency has also identified special controls for these devices. On or before the effective date of this final rule, firms who wish to market external eyelid weight devices that are not already legally marketed are required to either (1) comply with the particular mitigation measures set forth in the special

controls in § 886.5700(b)(1) 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. As discussed in sections IV and V, in response to comments regarding compliance with the special controls for existing legally marketed devices, FDA has extended the compliance date for special controls to 1 year from the effective date of this rule to allow manufacturers of existing legally marketed devices adequate time to review the design history files and complete any needed testing and implement any required labeling changes for their devices.

FDA also made changes to the final rule as related to external eyelid weights in response to the comments and for clarification. Proposed § 886.5700(b)(1)(iii) has been edited to remove the words "required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter" to minimize any confusion since this section describes special controls and the labeling requirements in 21 CFR part 801 are a general control. FDA also removed the special controls for external eyelid weights related to magnetic resonance (MR) compatibility testing (see additional discussion in section IV).

B. Implantable Eyelid Weights

FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of implantable eyelid weights, and, therefore, this device type is not exempt from premarket notification requirements. The Agency has also identified special controls for these devices. On or before the effective date of this final rule, firms who wish to market external eyelid weight devices that are not already legally marketed are required to either (1) comply with the particular mitigation measures set forth in the special controls in § 886.5700(b)(2) 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. As discussed in section IV, in response to comments regarding compliance with the special controls for existing legally marketed devices, FDA has extended the compliance date for special controls to 1 year from the effective date of this rule to allow manufacturers of existing legally marketed devices adequate time to review the design history files and complete any needed testing and implement any required labeling changes for their devices.

IV. Analysis of Comments and FDA's Response

FDA received three comments on the proposed rule. One of the comments was supportive of FDA's proposed rule, including the classification and the special controls for both the external and implantable eyelid weights and the exemption of external eyelid weights from premarket notification requirements (510(k)). A second comment agreed with the proposed classification into class II, but indicated that the risks associated with long-term use of external eyelid weights were similar to those for implantable eyelid weights, and that as such external eyelid weights should not be exempted from the premarket notification requirements. FDA disagrees with the comment. FDA believes that the identified special controls adequately mitigate the risks to health for the device regardless of the duration of use. The increased risks associated with implanted eyelid weights are related to the need for the device to be provided sterile and the increased biocompatibility requirements. These risks are significantly reduced with external eyelid weight devices. FDA believes that compliance with the special controls in § 886.5700(b)(1) provides a reasonable assurance of safety and effectiveness for external eyelid weight devices without the need for premarket notification.

The third comment requested clarification on whether existing eyelid weight manufacturers (for both implantable and external eyelid weight devices) need to address the identified special controls. The special controls established in this rule apply to existing legally marketed devices, as well as to new eyelid weight devices not currently marketed for which marketing authority is sought and to any modification of a currently legally marketed eyelid weight. In response to this comment, FDA has extended the compliance date for special controls for manufacturers of existing legally marketed devices to 1 year from the effective date of this rule, as outlined in section V, "Compliance Dates."

Submission of a new 510(k) solely to demonstrate conformance to the special controls is not needed unless complying with the special controls leads to changes to the device that would independently trigger the need for a new 510(k) under § 807.81(a)(3). However, manufacturers should maintain documentation in their design history file (see § 820.30 (21 CFR 820.30)) to demonstrate that they meet the special controls. To ensure that manufacturers of existing legally marketed devices have adequate time to review their design history files and complete any needed testing and implement any required labeling changes for their devices, FDA has extended the compliance date for existing legally marketed devices to comply with the special controls to 1 year after the effective date of this final rule. Manufacturers with questions regarding their existing devices are encouraged to interact with FDA via the pre-submission process.

The third comment further suggested that the biocompatibility testing requirements as described in the proposed special controls are more extensive and burdensome than the requirements under which existing legally marketed eyelid weights devices were originally reviewed. The comment stated that, for external eyelid weights, limited biocompatibility testing with supportive literature review and reference to material in predicate devices should be

acceptable in lieu of a full battery of biocompatibility testing. FDA agrees that based on the material and manufacturing processes being used, a full battery of biocompatibility testing may not be required. Discussion of the specific biocompatibility testing requirements for existing legally marketed eyelid weight devices is beyond the scope of this rule; however, FDA encourages manufacturers to review existing Agency guidance on this topic and contact FDA via the pre-submission process to discuss specific biocompatibility requirements for their devices.

The third comment further requested clarification on whether a labeling change to address MR compatibility would trigger additional compliance expectations regarding MR testing and suggested that because external eyelid weights are removable devices, MR compatibility should not be a requirement for these devices. FDA agrees with the commenter that removal of the device when the patient is in the MR environment would mitigate this risk and has thus removed MR testing compatibility testing as a special control. However, to ensure that the patient is aware that the device should be removed in these circumstances, the special control regarding labeling has been revised to include a requirement for a warning stating that the patient should be instructed to remove the device prior to entering an MR environment.

Finally, the third comment also requested clarification on the special control for implanted eyelid weights: “testing demonstrating the sterility and shelf life of the device” and suggested that the shelf life of the implanted device is limited by the ability of the associated packaging to maintain a protective barrier and not by the device itself, and therefore, validated packaging and sterilization procedures would satisfy this requirement. Although FDA agrees that validation of the packaging and sterilization processes is important to comply with this special control, each manufacturer must assess the materials and processes used to manufacture

their device when determining the testing necessary to provide assurance that the sterility and functionality of the device are maintained over its shelf life.

V. Compliance Dates

This final rule will become effective [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

The special controls established in this rule for external eyelid weights and the special controls established in this rule for implantable eyelid weights apply to any external or implantable eyelid weight respectively, whether the device is an existing legally marketed device, a new eyelid weight device not currently marketed for which marketing authority is sought, or a modification of a currently legally marketed eyelid weight. Devices of this type that were legally marketed before the effective date of this rule may continue to be legally marketed; however 1 year after the effective date of this rule, such devices must comply with applicable special controls in order to continue to be legally marketed. Submission of a new 510(k) solely to demonstrate conformance to the special controls is not needed unless complying with the special controls leads to changes to the device that would independently trigger the need for a new 510(k) under § 807.81(a)(3). However, manufacturers should maintain documentation in their design history file (see § 820.30(j)) to demonstrate that they meet the special controls. One year after the effective date of this rule, any external eyelid weight that does not comply with the special controls established in § 886.5700(b)(1) or implantable eyelid weight that does not comply with the special controls established in § 886.5700(b)(2) this rule will be considered adulterated and misbranded (sections 501(f)(1)(B) and 502(o) of the FD&C Act (21 U.S.C. 351(f)(1)(B) and 352(o)) until such time as the device: (1) Complies with the special controls

and any premarket notification requirements; (2) is approved in a PMA application; or (3) is classified into class I or II under section 513(f)(2) or (3) of the FD&C Act.

A 510(k) submission for an eyelid weight either filed before the effective date of this rule, but not yet cleared for marketing or filed after the effective date of this rule may be cleared for marketing only if the device complies with the special controls established for this device type. The submitter may demonstrate that the special controls have been met by incorporating previously submitted information by reference, or by providing newly generated information. A submitter's first 510(k) submission for an implantable eyelid weight filed following the publication of this final rule should be a traditional 510(k) submission. Filing of a special 510(k) submission for a modified implantable eyelid weight is only appropriate after FDA has cleared an initial 510(k) submission that establishes that the device complies with the special controls established for the device type.

VI. 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.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct 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 not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final regulation classifies a previously unclassified pre-amendment device type, there are only five registered establishments listed in the Establishment Registration and Device Listing database, and the regulation designating the classification of eyelid weights as class II is consistent with the historical regulatory oversight given to this device type, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VIII. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to currently approved collections of information found in other 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 807, subpart E,

have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886--OPHTHALMIC DEVICES

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

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

2. Add § 886.5700 to subpart E to read as follows:

§ 886.5700 Eyelid weight.

(a) Identification. An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

(1) The external eyelid weight is adhered to the outer skin of the upper eyelid.

(2) The implantable eyelid weight is implanted into the upper eyelid.

(b) Classification. (1) Class II (special controls) for the external eyelid weight. The external eyelid weight is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9. The special controls for the external eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device; and

(ii) Labeling must include the following information:

(A) Specific instructions regarding the proper placement, sizing, and removal of the device; and

(B) A warning stating that the patient should be instructed to remove the device prior to entering a magnetic resonance environment.

(2) Class II (special controls) for the implantable eyelid weight. The special controls for the implantable eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device;

(ii) Testing demonstrating the sterility and shelf life of the device;

(iii) Nonclinical testing evaluating the compatibility of the device in a magnetic resonance environment.

(iv) Patient labeling to convey information regarding the safety and compatibility of the device in a magnetic resonance environment, the conditions under which a patient with the device can be safely scanned, and a mechanism for a healthcare provider to obtain detailed information about magnetic resonance safety and compatibility if needed.

Dated: April 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-08940 Filed 04/18/2014 at 8:45 am; Publication Date: 04/21/2014]