4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2012-N-1238]

Medical Devices; Ophthalmic Devices; Classification of the Scleral Plug

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the scleral plug into class II (special controls), and exempting the scleral plugs composed of surgical grade stainless steel (with or without coating in gold, silver, or titanium) from premarket notification (510(k)) and continuing to require premarket notification (510(k)) for all other scleral plugs in order to provide a reasonable assurance of safety and effectiveness of the device. The scleral plug is a prescription device used to provide temporary closure of a scleral incision during an ophthalmic surgical procedure.

DATES: This final rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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) (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), Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85), and 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, 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 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. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of scleral plugs if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating.

II. Regulatory History of the Device

In the Federal Register of January 25, 2013 (78 FR 5327), FDA proposed to classify scleral plug devices used to provide temporary closure of a scleral incision during an ophthalmic surgical procedure 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 made from surgical grade stainless steel (with or without a gold, silver, or titanium coating).

FDA invited interested persons to comment on the proposed regulation by April 25, 2013. FDA received no comments on the proposed rule.

III. Summary of Final Rule

In accordance with 21 CFR 860.84(g)(2), FDA is classifying scleral plugs into class II (special controls). FDA is codifying the classification of scleral plugs by adding § 886.4155. The Agency is also exempting these devices from premarket notification requirements when they are made from surgical grade stainless steel (with or without a gold, silver, or titanium coating). The Agency has also identified special controls for scleral plug devices. Following the effective date of this final classification rule, manufacturers will need to address the issues covered by these special controls.

IV. Analysis of Comments and FDA's Response

FDA received no comments on the proposed rule. Therefore, under section 513 of the FD&C Act, FDA is adopting the proposed classification and FDA's finding. FDA is also adopting the assessment of the risks to public health stated in the proposed rule published on January 25, 2013. FDA is issuing this final rule which classifies the generic type of device, scleral plugs, into class II (special controls). In addition, FDA, on its own initiative, is exempting scleral plugs made from surgical grade stainless steel (with or without a gold, silver, or titanium coating) from premarket notification requirements.

V. 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.

VI. 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 (Public Law 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 preamendment device type, there are only five registered establishments listed in the Establishment Registration and Device Listing database, and the regulation designating the classification of scleral plugs 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.

VII. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to previously 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 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; the collections of information in part 807, subparts B and C, have been approved under OMB control number 0910-0387.

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. In subpart E, add § 886.4155 to read as follows:

§ 886.4155 Scleral plug.

(a) Identification. A scleral plug is a prescription device intended to provide temporary closure of a scleral incision during an ophthalmic surgical procedure. These plugs prevent intraocular fluid and pressure loss when instruments are withdrawn from the eye. Scleral plugs include a head portion remaining above the sclera, which can be gripped for insertion and removal, and a shaft that fits inside the scleral incision. Scleral plugs are removed before completing the surgery.

(b) Classification. Class II (special controls). The special controls for the scleral plug are as follows:

(1) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9 if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating. The special controls for the surgical grade stainless steel scleral plug (with or without a gold, silver, or titanium coating) are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible; and

(iii) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

(2) The device is not exempt from premarket notification procedures if it is composed of a material other than surgical grade stainless steel (with or without a gold, silver, or titanium coating). The special controls for scleral plugs made of other materials are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible;

(iii) Characterization of the device materials must be performed;

(iv) Performance data must demonstrate acceptable mechanical properties under simulated clinical use conditions including insertion and removal of the device;

(v) Performance data must demonstrate adequately low levels of the extractables or residues from manufacturing (or processing) of the device; and

(vi) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

Dated: November 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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