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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to classify the scleral plug into class II (special controls), and proposing to exempt the scleral plugs composed of surgical grade stainless steel (with or without coating in gold, silver, or titanium) from premarket notification (510(k)) and to continue 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: Submit either electronic or written comments by April 25, 2013. See section IV of this document for the proposed effective date of a final rule that may issue based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–1238, 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 way:

- *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–1238 for this rulemaking. 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, 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: 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

A. Statutory and Regulatory Authorities

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), 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 (21 U.S.C. 360c(f)) 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 (21 U.S.C. 360c(i)), 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 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.

B. Regulatory History of the Device

After the enactment of the Medical Device Amendments of 1976, FDA commenced to identify and classify all preamendments devices, in accordance with section 513(b) (21 U.S.C. 360c(b)) of the FD&C Act. In the **Federal Register** of September 2, 1987 (52 FR 33346), FDA classified a total of 109 generic types of ophthalmic devices. The scleral plug was not identified in this initial effort. FDA has regulated scleral plugs as devices requiring premarket notification (510(k)). Scleral plugs currently on the market have been determined to be substantially equivalent to devices that were in commercial distribution prior to May 28, 1976. Currently, FDA regulates scleral plugs as devices requiring premarket notification (510(k)). There have been ten 510(k) submissions received and cleared under product code LXP (scleral plugs).

Consistent with the FD&C Act and the regulations, FDA consulted with the Ophthalmic Devices Panel (the Panel), an FDA advisory committee, regarding

the classification of this device type on January 22, 1996 (Ref. 1). At the panel meeting, the Panel recommended scleral plugs as classification as class I, 510(k) exempt. Two 510(k) submissions have been cleared since the panel meeting.

II. Recommendation of the Panel

During a public meeting which was held on January 22, 1996, the Panel made recommendations regarding the classification and regulatory controls for the scleral plug. FDA is proposing the following identification based on the Panel's recommendations and the Agency's review:

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. Therefore, they are generally only used in operating rooms. These devices are often made of surgical grade stainless steel and can be coated in gold, silver, or titanium.

Scleral plugs have a long and established history of clinical use. They are routinely used in many ophthalmic surgeries (specifically, vitreoretinal surgeries). One common type of vitreoretinal surgery is vitrectomy. Vitrectomy is estimated to be the third most frequently performed ophthalmic surgical operation, after cataract and excimer laser refractive surgery (Ref. 2). Approximately 225,000 vitrectomies are done in the United States each year (Ref. 2).

B. Recommended Classification of the Panel

Although the Panel was informed that scleral plugs have historically been treated as class II devices, the Panel recommended that a scleral plug made of a material previously used in legally marketed devices be classified into class I (general controls) and be exempt from premarket notification because the biocompatibility and ability to be sterilized have already been established. The Panel's rationale for suggesting that the scleral plug be classified into class I was because general controls would provide reasonable assurance of the safety and effectiveness of the device type if it is made from a material established to be readily sterilized and biocompatible. During the panel discussion, a distinction was made that scleral plugs consisting of other materials (i.e., materials that are not already included in legally marketed medical devices to the date of the classification regulation) should be classified into class II and require biocompatibility testing as a special control.

As a result of the distinction between materials used for this device, the Panel recommended that, unless new materials are proposed, the device should be exempt from premarket notification.

C. Summary of Reasons for Recommendation

The Panel considered FDA's extensive regulatory experience with the device type and the Panel members' personal knowledge of and clinical experience with the device type. The Panel also considered the long history of safety and effectiveness of the device over many years of clinical use. The Panel recommended that the scleral plug be classified into class I because it concluded that general controls would provide reasonable assurance of the safety and effectiveness of the device type if it was made from a material established to be readily sterilized and biocompatible. The Panel also recommended that scleral plugs be exempt from premarket notification requirements if the proposed device does not introduce new materials (i.e., materials that are not established to be safe for this type of application).

However, FDA believes that a class II classification is appropriate and consistent with the intent of the Panel to establish requirements (such as biocompatibility and sterility) for these devices. Although the Panel identified potential risks and the measures that could be taken to mitigate these risks, the Panel's recommendation of class I would not permit FDA to establish as special controls the mitigation measures discussed (biocompatibility, sterility). Therefore, while FDA is not adopting the Panel's recommendation of classification into class I, the Agency agrees with the concerns and mitigation measures discussed by the Panel that would support a classification under class II.

D. Risks to Health

Based on the Panel's discussion and recommendations and FDA's experience with the device, the risks to health associated with the scleral plugs made from surgical grade stainless steel with or without gold, silver, or titanium coating and the proposed measures to mitigate these risks are identified in table 1 of this document.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR THE SCLERAL PLUG MADE FROM SURGICAL GRADE STAINLESS STEEL

[With or without a gold, silver, or titanium coating]

Identified risk	Mitigation measures
Infection	Sterility Testing.
Adverse Tissue Reaction.	Biocompatibility Testing.
Loss, breakage, or migration of the plug.	Labeling.

For scleral plugs that are made of surgical grade stainless steel (with or without a gold, silver, or titanium coating) the following special controls, in addition to general controls, can address the risks to health in table 1 of this document and provide reasonable assurance of safety and effectiveness of the device: (1) Performance data must demonstrate the sterility and shelf life of the device; (2) the device must be demonstrated to be biocompatible; and (3) labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper incision size, placement, and removal of the device.

Because of the varying properties of other materials and the potential impact on safety and effectiveness, FDA has identified additional special controls for devices made of materials other than surgical grade stainless steel. Based on the Panel's discussion and recommendations and FDA's experience with the device, the risks to health associated with the scleral plugs made from materials other than surgical grade stainless steel and the proposed measures to mitigate these risks are identified in table 2 of this document.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR SCLERAL PLUGS MADE FROM MATERIALS OTHER THAN SURGICAL GRADE STAINLESS STEEL

Identified risk	Mitigation measures
Infection	Sterility Testing. Shelf-life Testing.
Adverse Tissue Reaction.	Biocompatibility testing. Material characterization. Performance testing to determine the level of extractables.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR SCLERAL PLUGS MADE FROM MATERIALS OTHER THAN SURGICAL GRADE STAINLESS STEEL—Continued

Identified risk	Mitigation measures
Loss, breakage, or migration of the plug.	Material characterization. Performance testing for Mechanical Properties. Labeling.

The Agency believes that the following special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness for scleral plugs that are composed of a material other than surgical grade stainless steel, as outlined in table 2: (1) Performance data must demonstrate the sterility and shelf life of the device; (2) the device must be demonstrated to be biocompatible; (3) characterization of the device materials must be performed; (4) performance data must demonstrate acceptable mechanical properties under simulated clinical use conditions including insertion and removal of the device; (5) performance data must demonstrate adequately low levels of the extractables or residues from manufacturing (or processing) of the device; and (6) labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper incision size, placement, and removal of the device. In addition, the scleral plug is a prescription device and must be used in accordance with 21 CFR 801.109.

III. Proposed Classification and FDA's Finding

Adverse events involving scleral plugs are rare, as evidenced by the fact that FDA identified only a single adverse event in our reporting systems and two adverse events in the published literature (Refs. 3 and 4). The one adverse event reported to FDA resulted in no persistent adverse effects to the patient and, according to the report, this specific type of non-metallic scleral plug was discontinued and replaced with surgical grade stainless steel scleral plugs.

FDA believes that a class II classification is consistent with the intent of the Panel to establish requirements (such as biocompatibility and sterility) for these devices. The identified special controls mitigate the known risks of the device that were identified by the Panel. However, the FDA does not agree with the Panel that all materials included in legally marketed scleral devices can be exempted from 510(k) due to the potential for safety concerns in some materials that will require specific material information and performance data to provide a reasonable assurance of safety and effectiveness. FDA believes this type of information should be reviewed by FDA prior to a device being marketed in the United States.

FDA proposes the scleral plug be classified into class II. The special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device. FDA also agrees, in part, with the Panel's recommendation that premarket notification is not necessary to assure the safety and effectiveness of scleral plugs if new materials are not introduced and, therefore, the Agency is giving notice of intent to exempt the scleral plug device from premarket notification requirements if the device is made from surgical grade stainless steel (with or without a gold, silver, or titanium coating).

IV. Proposed Effective Date

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

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 proposed rule under Executive Order 12866 and 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 proposed rule is not a significant regulatory action as defined by 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 proposed regulation will classify a previously unclassified pre-Amendment device type, there are only five registered establishments listed in the Establishment Registration and Device Listing database, and the proposed regulation designating the classification of scleral plugs as class II is consistent with the historical regulatory oversight given to this device type, the Agency proposes to certify 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 $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The proposed rule would impact current manufacturers if they were to make changes to their existing products and any manufacture wanting to market a new scleral plug. If the new or changed product is made of surgical grade stainless steel with or without gold, silver, or titanium coating, manufacturers could begin marketing after they complied with the proposed special controls. They would not need to submit an application to the Agency for preapproval. There would be no change from current requirements for new products made of alternative materials; they would need premarket notification before marketing.

VII. Paperwork Reduction Act of 1995

This proposed 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; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0387.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses of the following references, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Transcript from the Food and Drug Administration Ophthalmic Devices Panel Meeting, January 22, 1996.

2. Chang, Stanley, ''LXII Edward Jackson Lecture: Open Angle Glaucoma After Vitrectomy,'' *American Journal of Ophthalmology,* vol. 141(6): pp. 1033–1043, June 2006, available at *http://www.sciencedirect.com/science/article/pii/S0002939406002546.*

3. Stewart, M. W., ''Intraoperative Radiographic Detection of a 'Lost' Scleral Plug,'' *Retina,* vol. 25(4): pp. 526–527, June 2005.

4. Bovino, J. A. and D. F. Marcus, ''Intraocular Foreign-Body Hazard During Vitrectomy,'' *American Journal of Ophthalmology,* vol. 93 (3): p. 366, March 1982.

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, FDA proposes to amend part 886 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:

(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: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01447 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

Proposed Priorities and Definitions—NIDRR DRRP—Community Living and Participation, Health and Function, and Employment of Individuals With Disabilities

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priorities and definitions.

CFDA Numbers: 84.133A–3, 84.133A–4, and 84.133A–5.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes funding priorities and definitions for the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this document proposes priorities for a Disability and Rehabilitation Research Project (DRRP) on Community Living and Participation of Individuals with Disabilities (Proposed Priority 1), a DRRP on Health and Function of Individuals with Disabilities (Proposed Priority 2), and a DRRP on Employment of Individuals with Disabilities (Proposed Priority 3). If an applicant proposes to conduct research under these priorities, the research must be focused on one of the four stages of research. This document proposes definitions for the four stages of research: exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation. The Assistant Secretary may use one or more of these priorities and definitions for competitions in fiscal year (FY) 2013 and later years. We take this action to focus research attention on areas of national need. We intend these priorities and definitions to contribute to improved employment and independent living outcomes for individuals with disabilities.

DATES: We must receive your comments on or before February 25, 2013.

ADDRESSES: Address all comments about this document to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue SW., Room 5133, Potomac