

for the Board to solicit comment on the effect of the proposal on small entities. The Board will, if necessary, conduct a final regulatory flexibility analysis after consideration of comments received during the public comment period.

1. *Statement of the need for, and objectives of, the proposed rule.* Title X of the Dodd-Frank Act transferred rulemaking authority for the S.A.F.E. Act and other enumerated consumer financial protection laws from the Board to the Bureau, effective July 21, 2011. In December 2011, the Bureau issued an Interim Final Rule to incorporate the S.A.F.E. Act pursuant to the transfer of rulemaking authority. Although the Board retains authority to issue some consumer financial protection rules, all rulemaking authority under the S.A.F.E. Act concerning mortgage loan originator registration was transferred to the Bureau. Consequently, the Board is proposing to repeal its regulations that incorporated the S.A.F.E. Act.

2. *Small entities affected by the proposed rule.* Any entity that is currently covered by the S.A.F.E. Act is subject to the rules issued by the Bureau, located in 12 CFR part 1007 and 1008. Therefore the Board's repeal of its regulations that incorporated the S.A.F.E. Act would not affect any entity, including small entities.

3. *Recordkeeping, reporting, and compliance requirements.* The proposed rule would repeal parts of the Board's regulations that incorporated the S.A.F.E. Act, and would therefore not impose any recordkeeping, reporting, or compliance requirements on any entities.

4. *Other Federal Rules.* The Board has not identified any federal rules that duplicate, overlap, or conflict with the proposed repeal of the Board's regulations that incorporated the S.A.F.E. Act.

5. *Significant alternatives to the proposed revisions.* The Board is not aware of any significant alternatives that would further minimize the impact on small entities of the proposed repeal, but solicits comment on this approach.

III. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board reviewed the rule under the authority delegated to the Federal Reserve by the Office of Management and Budget (OMB). The proposed rule contains no collections of information under the PRA. See 44 U.S.C. 3502(3). Accordingly, there is no paperwork burden associated with the proposed rule.

List of Subjects

12 CFR Part 208

Accounting, Agriculture, Banks, Banking, Confidential business information, Consumer protection, Crime, Currency, Insurance, Investments, Mortgages, Reporting and recordkeeping requirements, Securities.

12 CFR Part 211

Exports, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth in the preamble, the Board proposes to amend chapter II of title 12 of the Code of Federal Regulations as follows:

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM (REGULATION H)

- 1. The authority citation for part 208 continues to read as follows:

Authority: 12 U.S.C. 24, 36, 92a, 93a, 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1818, 1820(d)(9), 1833(j), 1828(o), 1831, 1831o, 1831p–1, 1831r–1, 1831w, 1831x, 1835a, 1882, 2901–2907, 3105, 3310, 3331–3351, 3905–3909, and 5371; 15 U.S.C. 78b, 78l(b), 78l(i), 780–4(c)(5), 78q, 78q–1, and 78w, 1681s, 1681w, 6801, and 6805; 31 U.S.C. 5318; 42 U.S.C. 4012a, 4104a, 4104b, 4106 and 4128.

Subpart I—[Removed and Reserved]

- 2. Remove and reserve subpart I, consisting of §§ 208.101 through 208.105 and Appendix A.

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

- 3. The authority citation for part 211 continues to read as follows:

Authority: 12 U.S.C. 221 *et seq.*, 1818, 1835a, 1841 *et seq.*, 3101 *et seq.*, 3901 *et seq.*, and 5101 *et seq.*; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

- 4. In § 211.24, remove paragraph (k).

By order of the Board of Governors of the Federal Reserve System, September 20, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–20832 Filed 9–24–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2018–N–3074]

Ophthalmic Devices; Reclassification of Ultrasound Cyclodestructive Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing this proposed order to reclassify the ultrasound cyclodestructive device, a postamendments class III device (regulated under product code LZR), into class II (special controls), subject to premarket notification. FDA is also identifying the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. If finalized, this order will reclassify these devices from class III to class II (special controls) and reduce regulatory burdens as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

DATES: Submit either electronic or written comments on the proposed order by November 26, 2018. Please see section XI for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 26, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-3074 for "Ophthalmic Devices; Reclassification of Ultrasound Cyclodestructive Device." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1652, Silver Spring, MD 20993, 301-796-6351, hina.pinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes 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).

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)(1) 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 21 CFR part 807.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

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 regulatory authority (see *Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in "medical science" (*Upjohn v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the "new information" to support reclassification under section 513(f)(3) of the FD&C Act 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 Assoc. 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 PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c))). Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to

reasonably assure the safety and effectiveness of the device.

II. Regulatory History of the Devices

On June 30, 1988, FDA approved the first and only ultrasound cyclodestructive device through its PMA process under section 515 of the FD&C Act (21 U.S.C. 360e). On August 10, 1988 (53 FR 30101), FDA announced a PMA order for Sonocare Inc.'s Model CST-100 Therapeutic Ultrasound System (Sonocare CST-100) (Ref. 1). As of the date of issuance of this proposed order, the Sonocare CST-100 is the only PMA approved by FDA for this device type.

III. Device Description

An ultrasound cyclodestructive device is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. An ultrasound cyclodestructive device is indicated for the treatment of refractory glaucoma; it is intended for patients who are refractory to or are poor candidates for laser or surgical treatment and fail to achieve target intraocular pressures on maximally tolerated drug therapy. The device is designed to reduce intraocular pressure by producing a series of lesions in the ciliary body and trabecular meshwork induced by high intensity focused ultrasound (HIFU) energy. Different technologies, such as laser cyclodestruction to lower intraocular pressure, have been studied since the 1970s (Refs. 2 and 3), which increases FDA's knowledge base for devices used to treat this condition. As stated earlier in section II, FDA has approved only one ultrasound cyclodestructive device through its PMA process under section 515 of the FD&C Act (Ref. 4). More recently, reports in the literature indicate that the HIFU technology has been modified and currently studied in Europe for treatment of refractory glaucoma (Refs. 5 to 8). Based upon our review experience and consistent with the FD&C Act and FDA's regulations, FDA believes that these devices should be reclassified from class III into class II because there is sufficient information to establish special controls that can provide reasonable assurance of the device's safety and effectiveness.

Conventional refractory glaucoma treatment modalities include implantable aqueous shunts and valves, trabeculectomy and other incisional glaucoma surgeries, cyclocryotherapy, as well as laser transcleral cyclophotocoagulation. FDA currently regulates all of the devices indicated for these procedures in a refractory

glaucoma population as class II devices, subject to 510(k) requirements.

IV. Proposed Reclassification

On April 29, 2015, FDA published a document in the **Federal Register** entitled "Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection," in which FDA announced plans to consider reclassifying ultrasound cyclodestructive devices identified with the LZR product code from class III to class II (80 FR 23798) and requested comments. FDA received no adverse comments regarding our proposed intent for LZR.

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify this postamendments class III device into class II. FDA believes that there is sufficient information available to FDA through peer-reviewed literature and knowledge of similar devices to establish special controls that would effectively mitigate the risks to health identified in section V. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA is proposing to create a separate classification regulation for ultrasound cyclodestructive devices that will be reclassified from class III to II. Under this proposed order, if finalized, the ultrasound cyclodestructive devices will be identified as a prescription device. As such, the prescription device must satisfy prescription labeling requirements (see § 801.109 (21 CFR 801.109), *Prescription devices*). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and § 801.5 (21 CFR 801.5), as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). In this proposed order, if finalized, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, will provide a reasonable assurance of the safety and effectiveness for ultrasound cyclodestructive devices.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification

is necessary for ultrasound cyclodestructive devices to provide reasonable assurance of safety and effectiveness. Therefore, the Agency does not intend to exempt these proposed class II devices from 510(k) requirements. Persons who intend to market this type of device must submit to FDA a 510(k) and receive clearance prior to marketing the device.

This proposal, if finalized, will decrease regulatory burden and will reduce private costs and expenditures required to comply with Federal regulations. Specifically, regulated industry will no longer have to submit a PMA but can instead submit a 510(k) to the Agency for review prior to marketing their device. A 510(k) is a less burdensome pathway to market a device, which typically results in a more timely premarket review compared to a PMA and reduces the regulatory burden in addition to providing more timely access of these types of devices to patients.

V. Risks to Health

After considering the information available to FDA through the review submission, peer-reviewed literature, and knowledge of other technologies indicated to treat the same refractory glaucoma patient population (such as aqueous shunt and cryotherapy), FDA determined that the probable risks to health associated with the use of ultrasound cyclodestructive devices for treatment of refractory glaucoma are as follows:

- *Thermal Injury.* Exposure of the ocular tissue to the HIFU energy causes thermal damage of the tissue. The misdirection or misalignment of the beam may cause temperature elevation in the non-target ocular tissues and overall ocular tissue damage. Unsuitable power and duration of the beam may also result in temperature elevation, which may cause corneal lesions including scleral thinning, corneal ectasia and perforation, eyelid burns, corneal burns, clouding of the cornea (haze) and lens (cataract formation), and retinal and choroidal lesions.

- *Physical Injury.* Exposure of the ocular tissue to the HIFU energy can cause physical damage to the ocular tissue due to cavitation or other mechanical effects. These injuries could be caused by the suboptimal selection of the treatment parameters, misalignment/displacement of the probe during the treatment, device malfunction, or other factors affecting stability of treatment. For example, insonification of the zonular fibers may cause elongation or rupture of ligaments, which can lead to a displacement of the lens.

- *Post-treatment injury.* Post-treatment injury from use of the device may include intraocular inflammation (e.g., iritis, uveitis), increased intraocular pressure in the immediate post-treatment period, ciliary body hemorrhage, persistent or transient low pressure, decreased visual acuity, worsening glaucoma, phthisis, pain/discomfort, corneal edema, hyphema, retinal and choroidal complications, etc.

- *Electrical shock.* While in operation, the device may discharge electricity that could shock the user. Electrical shock can be caused by use error or device malfunction.

- *Electromagnetic interference.* While in operation, electromagnetic interferences from other devices operated in the same environment may cause the device to malfunction, which could result in patient's injury. In addition, the device may interfere with other electrically powered devices, causing them to malfunction.

- *Ocular irritation and corneal infections.* Inadequate biocompatibility of the eye contact components of the device can lead to irritation of the ocular tissue. Inappropriately sterilized or reprocessed eye contact components of the device can lead to inflammation and corneal infections.

VI. Summary of Reasons for Reclassification

FDA believes that the ultrasound cyclodestructive devices for treatment of refractory glaucoma should be reclassified from class III to class II in light of available information about the effectiveness of these devices. There is sufficient information to establish special controls for ultrasound cyclodestructive devices, in addition to general controls, which can provide reasonable assurance of safety and effectiveness of the device, as general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. FDA believes that the risks to health associated with ultrasound cyclodestructive devices for treatment of refractory glaucoma can be mitigated with special controls and that these mitigations will provide a reasonable assurance of its safety and effectiveness.

Based on a reconsideration of the available information and data, FDA believes that there is valid scientific evidence of effectiveness for ultrasound cyclodestructive devices to reduce intraocular pressure intended for treatment of refractory glaucoma using ultrasound.

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. Taking into account the probable health benefits of the use of the device and the nature and known incidence of the risks of the device, FDA, on its own initiative, is proposing to reclassify this postamendments class III device into class II. FDA has considered and analyzed the following information: An inclusive search of the Agency's Manufacturer and User Facility Device Experience (MAUDE) database, which shows no adverse events for ultrasound cyclodestructive device type; no recalls have been received for this device type; other technologies indicated to treat the same refractory glaucoma patient population, such as aqueous shunt and cryotherapy, and currently regulated as class II devices to compare the probable risks (i.e., between the rate and severity of the adverse events associated with these class II technologies and ultrasound cyclodestructive procedures); and peer-reviewed publications (Refs. 5 to 12) to identify probable device risks (e.g., the types and rates of adverse events) and mitigation strategies.

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are necessary and sufficient to mitigate the risks to health described in section V and provide a reasonable assurance of safety and effectiveness for ultrasound cyclodestructive devices.

- Non-clinical performance testing of device features and characteristics will demonstrate:

- The ability of the device to deposit controllable HIFU energy to the target area to evoke the required level of thermal lesion.

- The design and geometry of the HIFU transducer and the output characteristics of the HIFU generator, including operating frequency and power, produce a small focal zone and a steep transition of energy deposition between the focal zone and the untreated areas. In addition, the total acoustic power radiated by the transducer(s), spatial distribution of the ultrasound field (including compressional and rarefactional pressure), and spatial peak, temporal-average intensity will be evaluated. This may be accomplished by demonstrating compliance with the standard International Electrotechnical

Commission (IEC) Technical Specification (TS) 62556: Ultrasonics—Field characterization—Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems. Thermal and physical (due to potential cavitation of gas bubbles) safety analyses will also be evaluated.

- The appropriate alignment and focusing of the ultrasound beam to the target tissue to minimize unintended damage to adjacent ocular tissues.

- The function of all safety features built into the device, including the energy monitoring system.

- Clinical performance data will validate device performance and characterize ocular tissue thermal injuries, physical injury, and postoperative adverse events by establishing the treatment parameters for which the device is safe and effective.

- Electrical safety testing will minimize the risk of electrical shock, thermal or physical injury to the patient and healthcare provider. This may be accomplished by demonstrating compliance with FDA-recognized consensus standard American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) 60601-1: *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.*

- Electromagnetic compatibility testing ensures that electromagnetic interferences do not cause device malfunction. It can also provide assurance that electromagnetic interferences generated by the device do not affect the other devices operated in the same environment. This may be accomplished by demonstrating compliance with FDA-recognized consensus standard IEC 60601-1-2: *Medical electrical equipment, Part 1-2: General requirements for safety.* If the device incorporates radiofrequency (RF) wireless technology to perform medical functions and/or communicates medical data, testing will mitigate the risks associated with interference or degradation when using RF wireless technology. This may be accomplished by demonstrating compliance with FDA-recognized consensus standard AAMI TIR69: *Risk Management of Radio-frequency Wireless Coexistence for Medical Devices and Systems* (risk assessment) and ANSI/Institute of Electrical and Electronics Engineers (IEEE) C63.27: *American National Standard for Evaluation of Wireless Coexistence* (coexistence testing).

- Software verification, validation, and hazard analysis is necessary to

mitigate the risks of thermal and physical injury and ensures that software performs as intended and potential software malfunctions do not impact the safety or effectiveness of the device. If the device incorporates internet network connectivity, testing will demonstrate that cybersecurity concerns are mitigated (e.g., data integrity, unauthorized access, etc.).

- Biocompatibility evaluation can help mitigate the risk of ocular irritation and corneal infection by ensuring that the patient-contacting components of the device are safe for contact with skin and ocular tissue.

- Sterilization validation, for devices provided sterile, and/or cleaning validation, for devices or components that are reusable, help mitigate the risk of inflammation and corneal infections (e.g., keratitis).

- The labeling will also include necessary information to ensure safe and effective use of the ultrasound cyclodestructive device and minimize probability of the ocular treatment-related adverse events. Labeling needs to include sufficient information that will help the patient and healthcare

provider make an informed decision regarding treatment-related adverse effects of the ultrasound cyclodestructive treatment. For example, the labeling needs to include information regarding the most common reported treatment-related injuries, which may include intraocular inflammation (e.g., iritis, uveitis) and increased intraocular pressure in the immediate post-treatment period. Adverse event information related to ciliary body hemorrhage, persistent low pressure, decreased visual acuity, worsening glaucoma, phthisis, pain/discomfort, transient low pressure, corneal edema, hyphema, retinal complications (such as cystoid macula edema), and choroidal effusion or detachment need to be discussed. The labeling will mitigate the risk associated with the intraoperative events, such as pain/discomfort, and postoperative adverse events by providing appropriate clinical information along with mitigation strategies (e.g., retrobulbar or peribulbar anesthesia). Specifically, device labeling must include:

- Appropriate warnings and precautions to ensure safe and effective

use of the device and minimize potential device malfunctions and user errors.

- A summary of the clinical evaluation pertinent to use of the device, including study outcomes and adverse events.

- Information regarding procedure parameters, proper positioning of the HIFU transducer and its coupling with the eye, and typical course of treatment to ensure the user can safely operate the device.

- Validated reprocessing instructions to ensure the safe use of reusable device components.

- Safety information regarding electrical safety and electromagnetic compatibility to minimize risks to the patient and users.

Table 1 shows how FDA believes the risks to health identified and described in section V will be mitigated by the proposed special controls. This reclassification order and the identified special controls, if finalized, would provide sufficient detail regarding FDA's requirements to reasonably assure safety and effectiveness of ultrasound cyclodestructive devices.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR ULTRASOUND CYCLODESTRUCTIVE DEVICES

Identified risk to health	Mitigation measures
Thermal Injury	Non-clinical performance testing, Clinical performance data, Electrical Safety, Electromagnetic compatibility, Software verification, validation, and hazard analysis, Labeling.
Physical Injury	Non-clinical performance testing, Clinical performance data, Electrical safety, Electromagnetic compatibility, Software verification, validation, and hazard analysis, Labeling.
Post-treatment Injury	Non-clinical performance testing, Clinical performance data, Software verification, validation, and hazard analysis, Labeling.
Electrical Shock	Electrical safety, Labeling.
Electromagnetic Interference	Electromagnetic compatibility, Labeling.
Ocular Irritation and Corneal Infections	Biocompatibility evaluation, Sterility/reprocessing validation, Labeling.

In addition, FDA is proposing to limit these devices to prescription use under § 801.109. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and § 801.5, as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). Under 21 CFR 807.81, the device would continue to be subject to 510(k) requirements.

This reclassification order and the identified special controls, if finalized, would provide sufficient detail regarding FDA's requirements to reasonably assure safety and effectiveness of ultrasound cyclodestructive devices for the treatment of refractory glaucoma. As discussed below, the reclassification will be codified in 21 CFR 886.5350. FDA believes that adherence to the

proposed special controls, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of the devices.

IX. Analysis of 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.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This

proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XI. Proposed Effective Date

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

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**), and are available for viewing by interested persons between

9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as they are copyrighted or are available through the website address. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. PMA Database Reference for Sonocare. Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=319101>.
2. Shields, M.B., "Transcleral Diode Cyclophotocoagulation," in Chen, T.C. (ed.), "Surgical Techniques in Ophthalmology: Glaucoma Surgery." Saunders Elsevier, 2008.
3. Chen, T.C., L.R. Pasquale, D.S. Walton, et al., "Diode Laser Transcleral Cyclophotocoagulation." *International Ophthalmology Clinics*, 39(1):169–176, 1999.
4. Muratore, R.A., "History of the Sonocare CST-100: The First FDA-Approved HIFU Device." *Therapeutic Ultrasound*, 809:508–512, 2006.
5. Melamed, S., M. Goldenfeld, D. Cotlear, et al., "High-Intensity Focused Ultrasound Treatment in Refractory Glaucoma Patients: Results at 1 Year of Prospective Clinical Study." *European Journal of Ophthalmology*, 25(6):483–489, 2015.
6. Aptel, F., T. Charrel, C. Labon, et al., "Miniaturized High-Intensity Focused Ultrasound Device in Patients with Glaucoma: A Clinical Pilot Study." *Investigative Ophthalmology and Visual Science*, 52 (12):8747–8753, 2011.
7. Aptel, F. and C. Lafon, "Therapeutic Applications of Ultrasound in Ophthalmology." *International Journal of Hyperthermia*, 28(4):405–418, 2012.
8. Mastropasqua, R., V. Fasanella, A. Mastropasqua, et al., "High-Intensity Focused Ultrasound Circular Cyclocoagulation in Glaucoma: A Step Forward for Cyclodestruction?" *Journal of Ophthalmology*, (2017), 1–14, 2017.
9. Burgess, SE, R.H. Silverman, D.J. Coleman, et al., "Treatment of Glaucoma with High Intensity Focused Ultrasound." *Ophthalmology*, 93:831–838, 1986.
10. Coleman, D.J., F.L. Lizzi, J. Driller, et al., "Therapeutic Ultrasound in the Treatment of Glaucoma. II. Clinical Applications." *Ophthalmology*, 92:347–353, 1985.
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List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*, as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 886 be amended as follows:

PART 886—OPHTHALMIC DEVICES

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

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

- 2. Add § 886.5350 to subpart F to read as follows:

§ 886.5350 Ultrasound cyclodestructive device.

(a) *Identification.* An ultrasound cyclodestructive device is a prescription device to reduce intraocular pressure by producing a series of lesions in the ciliary body and trabecular meshwork induced by high intensity focused ultrasound (HIFU) energy and that is intended for treatment of refractory glaucoma.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The clinical performance data must demonstrate an adequate safety profile and an appropriate reduction in intraocular pressure in patients with refractory glaucoma and capture any adverse events observed during clinical use.

(2) Non-clinical performance testing of device features and characteristics must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Ultrasound field characteristics, which must include the total acoustic power radiated by the transducer(s), the spatial distribution of the ultrasound field (including compressional and rarefactional pressure), and spatial-peak, temporal-average intensity;

(ii) Thermal and physical safety characterization of the device; and

(iii) Simulated use testing to validate that the device performs as intended under anticipated conditions of use,

including eye movements and positioning error.

(3) Analysis/testing must demonstrate electrical safety in the appropriate use-environment.

(4) Analysis/testing must demonstrate electromagnetic compatibility (EMC), including wireless coexistence (if applicable) in the appropriate use-environment.

(5) Software verification, validation, and hazard analysis must be performed commensurate with the level of concern of the device.

(6) The patient-contacting components must be demonstrated to be biocompatible.

(7) Performance data must demonstrate sterility of all patient-contacting components labeled as sterile. If the device contains reusable eye-contact components, the validation tests must demonstrate adequate cleaning/reprocessing of these components.

(8) Labeling must include:

(i) A detailed description of the patient population for which the device is indicated for use, as well as warnings, and precautions regarding potential for device malfunction and use-error pertinent to use of the device.

(ii) A detailed summary of the clinical testing, including study outcomes and adverse events.

(iii) Information on how the device operates and the typical course of treatment.

(iv) Description of all main components of the device including HIFU generator, transducer(s), and controls. The labeling must include technical specification of the device including, but not limited to, treatment frequency, total acoustic power delivered by transducer, treatment duration, treatment zone, site targeting, power requirements, weight, and physical dimensions of the device.

(v) Where appropriate, validated methods and instructions for reprocessing of any reusable components.

(vi) Safe-use conditions for electrical safety and electromagnetic compatibility.

Dated: September 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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