(iii) Accurate positioning and alignment of the device to achieve fistula creation; and

(iv) Characterization and verification of all dimensions.

(4) Electrical performance, electrical safety, and electromagnetic compatibility (EMC) testing must be performed for devices with electrical components.

(5) Software verification, validation, and hazard analysis must be performed for devices that use software.

(6) All patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(8) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(9) Labeling for the device must include:

(i) Instructions for use;

(ii) Identification of system components and compatible devices;

(iii) Expertise needed for the safe use of the device;

(iv) A detailed summary of the clinical testing conducted and the patient population studied; and

(v) A shelf life and storage conditions.

Dated: February 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03496 Filed 2–17–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2022–N–0104]

Medical Devices; Ophthalmic Devices; Classification of the Electromechanical Tear Stimulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the electromechanical tear stimulator into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the electromechanical tear stimulator's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective February 18, 2022 . The classification was applicable on May 1, 2020.

FOR FURTHER INFORMATION CONTACT: Leonid Livshitz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1234, Silver Spring, MD 20993–0002, 301–796–6975, *Leonid.Livshitz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the electromechanical tear stimulator as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On May 15, 2019, FDA received Olympic Ophthalmics, Inc.'s request for De Novo classification of the iTEAR100 Neurostimulator. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the

safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 01, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 886.5305.[1] We have named the generic type of device electromechanical tear stimulator, and it is identified as a non-implantable device intended to increase tear production via mechanical stimulation.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ELECTROMECHANICAL TEAR STIMULATOR RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Tissue damage due to over stimulation/under stimulation or mechanical injury, device breakage.	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation, and Labeling.
Electrical shock or burn	Electrical, thermal, and mechanical safety testing; Software verification, validation, and hazard analysis; and Labeling.
Interference with other devices	Electromagnetic compatibility (EMC) testing; Software verification, validation, and hazard analysis; and Labeling.
Pain, headache, or discomfort	Clinical performance testing, and Non-clinical performance testing.
Insufficient tear production	Clinical performance testing.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801, regarding labeling, 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 part 886 continues to read as follows:

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

■ 2. Add § 886.5305 to subpart F to read as follows:

§ 886.5305 Electromechanical tear stimulator.

(a) *Identification.* An electromechanical tear stimulator is a non-implantable device intended to increase tear production via mechanical stimulation.

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

(1) Clinical performance testing under anticipated conditions of use must evaluate tear production and all adverse events, including tissue damage, pain, headache, and discomfort.

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

(i) An assessment of mechanical output specifications, including vibration amplitude and frequency, pressure and force, and acoustic (noise level) properties;

(ii) Mechanical safety testing to validate safeguards related to the pressure aspects of the device; and

(iii) Use life testing.

(3) Performance data must demonstrate the electrical safety, thermal safety, and electromagnetic compatibility (EMC) of all electrical components of the device.

(4) All patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

(6) Physician and patient labeling must include:

(i) A detailed summary of the device's technical parameters;

(ii) Instructions for use, including an explanation of all user-interface components and information regarding proper device placement;

(iii) Information related to electromagnetic compatibility classification;

(iv) Instructions on how to clean and maintain the device;

(v) A summary of the clinical performance testing conducted with the device;

(vi) Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device; and

(vii) Information on how the device operates and the typical sensations experienced during treatment.

Dated: February 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03540 Filed 2–17–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0126]

RIN 1625–AA00

Safety Zone; Coast Guard Island, Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Alameda Estuary, from surface to bottom, within 250 feet of the pier along the southwest side of Coast Guard Island in support of a munitions transfer on February 20, 2022. The safety zone is necessary to protect personnel, vessels, and the marine environment from the dangers associated with live munitions. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port San Francisco.

DATES: This rule is effective from 8 a.m. through 2 p.m. on February 20, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0126 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Anthony Solares, Sector San Francisco Waterways Safety Management, U.S. Coast Guard; telephone 415–399–3585, email *Anthony.I.Solares@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
CGC Coast Guard Cutter

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because munitions must be transferred for operational readiness. It is impracticable to publish an NPRM because we must establish this safety zone by February 20, 2022.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the munitions transfer near Alameda, CA beginning February 20, 2022.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) San Francisco has determined that potential hazards associated with the munitions transfer starting February 20, 2022 will be a safety concern for anyone within a 250-foot radius of the pier along the southwest side of Coast Guard Island. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the munitions transfer.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 a.m. until 2 p.m. on February 20, 2022. The safety zone will cover all waters of the Alameda Estuary, from surface to bottom, within 250 feet of the pier along the southwest side of Coast Guard Island. The safety zone is necessary to ensure the safety of people, vessels, and the marine environment for the duration of the munitions transfer. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the Alameda Estuary for only six hours. The Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a