

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 to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the *Trichomonas vaginalis* nucleic acid assay they intend to market.

## II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of 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.

## III. Paperwork Reduction Act of 1995

This final administrative order 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, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

### List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

### PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Add § 866.3860 to subpart D to read as follows:

#### § 866.3860 *Trichomonas vaginalis* nucleic acid assay.

(a) *Identification.* A *Trichomonas vaginalis* nucleic acid assay is a device that consists of primers, probes, enzymes, and controls for the amplification and detection of trichomonas nucleic acids in endocervical swabs, vaginal swabs, and female urine specimens, from women symptomatic for vaginitis, cervicitis, or urethritis and/or to aid in the diagnosis of trichomoniasis in asymptomatic women. The detection of trichomonas nucleic acids, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of trichomoniasis caused by *Trichomonas vaginalis*.

(b) *Classification.* Class II (special controls). The special controls are set forth in FDA's guideline document entitled: "Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*; Guideline for Industry and Food and Drug Administration Staff." See § 866.1(e) for information on obtaining this document.

Dated: July 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 874

[Docket No. FDA–2015–N–2525]

#### Medical Devices; Ear, Nose, and Throat Devices; Classification of the External Upper Esophageal Sphincter Compression Device

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the external upper esophageal sphincter (UES) compression device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the external UES compression device's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable

assurance of safety and effectiveness of the device.

**DATES:** This order is effective August 4, 2015. The classification was applicable on March 6, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Sunny Park, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2432, Silver Spring, MD, 20993–0002, 301–796–7059, [sunny.park@fda.hhs.gov](mailto:sunny.park@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(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 (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act.

If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On November 22, 2013, Somna Therapeutics, LLC, submitted a request for classification of the REZA BAND UES Assist Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies 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 to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 6, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 874.5900.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an external UES compression device will need to comply with the special controls named in this final order. The device is assigned the generic name external UES compression device, and it is identified as a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

FDA has identified the following risks to health associated specifically with

this type of device, as well as the mitigation measures required to mitigate these risks, in table 1.

**TABLE 1—EXTERNAL UES COMPRESSION DEVICE RISKS AND MITIGATION MEASURES**

Identified risk	Mitigation method
Adverse tissue reaction.	Biocompatibility assessment.
Risk of over-compression.	Clinical study. Labeling. Technical specifications.
Device misuse/incorrect fitting/malfunctions.	Technical specifications. Clinical study. Labeling. Performance testing (mechanical integrity and shelf life testing).

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

1. The patient contacting components must be demonstrated to be biocompatible.

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

a. Mechanical integrity testing (*e.g.*, tensile strength testing, fatigue testing) and

b. shelf life testing

3. The technical specifications must include pressure measurement accuracy to characterize device performance.

4. Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

5. Labeling must include the following:

a. Appropriate warnings and precautions.

b. A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events.

c. Detailed instructions on how to fit the device to the patient.

d. Instructions for reprocessing of any reusable components.

6. Patient labeling must be provided and must include:

a. Relevant warnings, precautions, and adverse effects/complications.

b. Information on how to correctly wear the device.

c. The potential risks and benefits associated with the use of the device.

d. Alternative treatments.

e. Reprocessing instructions.

The external UES compression device is a prescription device restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription 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), 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 to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the external UES compression device they intend to market.

## II. 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.

## III. Paperwork Reduction Act of 1995

This final order 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 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

## IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. DEN130046: De Novo Request per 513(f)(2) from Somna Therapeutics, LLC, dated November 11, 2013.

#### List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

#### PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for 21 CFR part 874 continues to read as follows:

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

■ 2. Add § 874.5900 to subpart F to read as follows:

##### § 874.5900 External upper esophageal sphincter compression device.

(a) *Identification.* An external upper esophageal sphincter compression device is a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

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

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

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

(i) Mechanical integrity testing (*e.g.*, tensile strength testing, fatigue testing) and

(ii) Shelf life testing.

(3) The technical specifications must include pressure measurement accuracy to characterize device performance.

(4) Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include the following:

(i) Appropriate warnings and precautions,

(ii) A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events,

(iii) Detailed instructions on how to fit the device to the patient, and

(iv) Instructions for reprocessing of any reusable components.

(6) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, and adverse effects/complications,

(ii) Information on how to correctly wear the device,

(iii) The potential risks and benefits associated with the use of the device,

(iv) Alternative treatments, and

(v) Reprocessing instructions.

Dated: July 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[Docket Number USCG–2015–0543]

RIN 1625-AA00; 1625-AA11

##### Safety Zones and Regulated Navigation Area; Shell Arctic Drilling/Exploration Vessel and Associated Voluntary First Amendment Area, Portland, OR

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary safety zones around Royal Dutch Shell's (Shell) contracted vessel FENNICA, which is participating in Shell's planned Arctic oil drilling and exploration operations, while it is located in the U.S. Territorial and Internal Waters of the Sector Columbia River Captain of the Port Zone. In addition, the Coast Guard is establishing a regulated navigation area to designate a Voluntary First Amendment Area for individuals that desire to exercise their First Amendment free speech rights with regards to Shell's operations. The safety zones and regulated navigation area created by this rule are necessary to ensure the mutual safety of all waterways users including the FENNICA and those individuals that desire to exercise their First Amendment rights.

**DATES:** This rule is effective without actual notice from August 4, 2015 until August 22, 2015. For the purposes of enforcement, actual notice will be used from July 22, 2015 until August 4, 2015.

**ADDRESSES:** Documents mentioned in this preamble are part of docket USCG–2015–0543 to view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket

number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Commander Laura Springer, Waterways Management Division, Coast Guard Marine Safety Unit Portland; telephone (503) 240–2594, email [Laura.M.Springer@uscg.mil](mailto:Laura.M.Springer@uscg.mil). If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

##### SUPPLEMENTARY INFORMATION:

##### Table of Acronyms

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking

##### A. Regulatory History and Information

The Coast Guard is issuing this temporary final 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 publishing an NPRM would be impracticable since the regulation is immediately necessary to help ensure the safety of all waterway users including the Shell contracted vessel FENNICA and those individuals that desire to exercise their First Amendment rights regarding Shell's activities and holding a notice and comment period at this time would delay regulatory implementation beyond the arrival of the FENNICA and expected start of First Amendment activities regarding Shell's operations, thereby increasing the safety risk to all waterways users.

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**. For reasons identical to those described above, delaying the effective