Dated: June 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2015–N–1297]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Vibrator for Climax Control of Premature Ejaculation; Republication

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; republication.

SUMMARY: The Food and Drug Administration (FDA) is republishing in its entirety a final order entitled ''Medical Devices; Gastroenterology-Urology Devices; Classification of the Vibrator for Climax Control of Premature Ejaculation'' that published in the **Federal Register** on May 28, 2015 (80 FR 30353). FDA is republishing to correct an inadvertent omission of information. FDA is classifying the vibrator for climax control of premature ejaculation 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 classification of the vibrator for climax control of premature ejaculation. 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 June 23, 2015. The classification was applicable on March 20, 2015.

FOR FURTHER INFORMATION CONTACT: Tuan Nguyen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G118, Silver Spring, MD 20993–0002, 301–796–5174, *tuan.nguyen@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) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (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) of the FD&C Act, the person requests a classification under section 513(f)(2). 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 21, 2013, Auris Medtech Europe, Ltd., submitted a request for classification of the Prolong™ under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1). On June 17, 2014, the request for classification of Prolong™ was transferred from Auris Medtech Europe, Ltd., to Ergon Medical, Ltd., through an amendment to the request (Ref. 2).

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 20, 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 876.5025.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a vibrator for climax control of premature ejaculation will need to comply with the special controls named in this final order. The device is assigned the generic name vibrator for climax control of premature ejaculation, and it is identified as a device used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

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

TABLE 1—VIBRATOR FOR CLIMAX CONTROL OF PREMATURE EJACULATION RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Pain or Discomfort due to Misuse of Device	Labeling.
Burns	Electrical and Thermal Safety Testing Labeling.
Electrical Shock	Electrical Safety Testing Labeling.
Adverse Skin Reactions	Biocompatibility Testing.
Patient Injury due to Device Breakage or Failure	Mechanical Safety Testing Labeling.
Interference With Other Devices/Electrical Equipment	Electromagnetic Compatibility Testing Labeling.

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:

- The labeling must include specific instructions regarding the proper placement and use of the device.
- The portions of the device that contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must demonstrate electromagnetic compatibility safety, electrical safety, and thermal safety of the device.
- Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

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 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 vibrator for climax control of premature ejaculation 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 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. References

The following references have 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 are available electronically at *http://www.regulations.gov.*

1. DEN130047: De Novo Request per 513(f)(2) from Auris Medtech Europe Ltd., dated November 21, 2013.

2. Amendment to De Novo Request from Auris Medtech Europe Ltd., dated June 17, 2014.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

■ 1. The authority citation for 21 CFR part 876 continues to read as follows:

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

■ 2. Republish § 876.5025 to read as follows:

§ 876.5025 Vibrator for climax control of premature ejaculation.

(a) *Identification.* A vibrator for climax control of premature ejaculation is used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

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

(1) The labeling must include specific instructions regarding the proper placement and use of the device.

(2) The portions of the device that contact the patient must be demonstrated to be biocompatible.

(3) Appropriate analysis/testing must demonstrate electromagnetic compatibility safety, electrical safety, and thermal safety of the device.

(4) Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

Dated: June 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15328 Filed 6–22–15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2013–0103]

RIN 1625–AA08

Regattas and Marine Parades; Great Lakes Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce various special local regulations for annual regattas and marine parades in the Captain of the Port Detroit zone from 9 a.m. on June 26, 2015 through 7 p.m. on August 23, 2015. Enforcement of these regulations is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after these regattas or marine parades. During the aforementioned period, the Coast Guard will enforce restrictions upon, and control movement of, vessels in a