reference source shall have sequence generated independently of the manufacturer with respect to technology and analysis. Percent agreement and percent disagreement with the reference sequences must be described for all regions queried by the instrument.

(C) If applicable, data describing endogenous or exogenous substances that may interfere with the instrument system.

(D) If applicable, data demonstrating the ability of the system to consistently generate an accurate result for a given sample across different indexing primer combinations.

(ix) The upper and lower limit of input nucleic acid that will achieve the claimed accuracy and reproducibility. Data supporting such claims must also be summarized.

Dated: March 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–04941 Filed 3–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2017–N–1123]

Medical Devices; Neurological Devices, Classification of the Vibratory Counter-Stimulation Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the vibratory counter-stimulation 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 vibratory counter-stimulation 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 March 14, 2017. The classification was applicable on December 18, 2013.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2640, Silver Spring, MD 20993–0002, 301–796–6476, *michael.hoffmann@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, also known as De Novo classification, 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 shall classify the device by written order within 120 days. This classification will be the initial classification of the device. In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on June 14, 2011, classifying the Symphony Device into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II.

On July 13, 2011, Sensory Medical, Inc. submitted a request for classification of the Symphony Device under section 513(f)(2) of the FD&C Act.

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 December 18, 2013, 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 882.5895.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a vibratory counter-stimulation device will need to comply with the special controls named in this final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or PMA in order to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome pathway of 510(k), when necessary, to market their device, and the device that was the subject of the original De Novo

classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name vibratory counter-stimulation device, and it is identified as a prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.

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—VIBRATORY COUNTER-STIMULATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measure
Pain, discomfort, worsening of Restless Legs Syndrome symptoms	Non-clinical testing, Software testing, Labeling.
Electrical shock	Electrical safety testing, Labeling.
Burns	Electrical and thermal safety testing, Labeling.
Adverse skin reactions	Biocompatibility assessment, Labeling.
Interference with other medical devices	Electromagnetic compatibility testing, Labeling.

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

Vibratory counter-stimulation devices are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (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 the device is not exempt from the premarket notification requirements of the FD&C Act. Persons who intend to market this type of device must submit a premarket notification (510(k)), prior to marketing the device, which contains information on the vibratory counter-stimulation device they intend to market.

II. 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.

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.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

■ 2. Add § 882.5895 to subpart F to read as follows:

§ 882.5895 Vibratory counter-stimulation device.

(a) *Identification.* A vibratory counter-stimulation device is a prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.

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

(1) Appropriate analysis/testing must demonstrate electromagnetic compatibility (EMC), electrical safety, and thermal safety.

(2) If the device contains software or firmware, appropriate verification, validation, and hazard analysis must be performed.

(3) The elements of the device that contact the patient must be assessed to be biocompatible.

(4) Non-clinical testing data (including vibration frequency, amplitude, and acceleration) must demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include:

(i) Specific information pertinent to use of the device by the intended patient population and the treatment regimen;

(ii) Warning to only use the device on normal, intact, clean, healthy skin;

(iii) Warning to not use the device if the user has leg skin disorders, such as eczema, psoriasis, cellulitis, non-healing wounds;

(iv) Warning to discontinue use if Restless Leg Syndrome symptoms worsen; and

(v) Instructions for end users to contact the device manufacturer and MedWatch in case they experience any adverse events when using this device.

Dated: March 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–04939 Filed 3–13–17; 8:45 am]

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COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Part 802

RIN 3225–AA12

Revision of Regulations Governing Freedom of Information Act Requests

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Interim final rule.

SUMMARY: This interim final rule updates and clarifies the procedures for submitting Freedom of Information Act (FOIA) requests as required under the *FOIA Improvement Act of 2016* (the 2016 Act) which was signed into law by the President on June 30, 2016. This rule makes the procedural changes necessitated by the 2016 Act, including