

(3) The following labeling must be provided:

(i) Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device.

(ii) Patient and physician labeling must list compatible devices.

(iii) Patient and physician labeling must include a warning that the device is not intended for use as a standalone therapy.

(iv) Patient and physician labeling must include a warning that the device does not represent a substitution for the patient's medication.

(v) Physician labeling must include a summary of the clinical testing with the device.

Dated: December 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2017-N-6531]

Medical Devices; Neurological Devices; Classification of the External Vagal Nerve Stimulator for Headache

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the external vagal nerve stimulator for headache 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 external vagal nerve stimulator for headache'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, in part by reducing regulatory burdens.

DATES: This order is effective December 27, 2017. The classification was applicable on April 14, 2017.

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SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the external vagal nerve stimulator for headache 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, in part by reducing regulatory burdens 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 (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 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 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). 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 shall 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.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 16, 2015, electroCore, LLC, submitted a request for De Novo classification of the gammaCore Non-invasive Vagus Nerve Stimulator. 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 April 14, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.5892. We have named the generic type of device

external vagal nerve stimulator for headache, and it is identified as a prescription device used to apply an electrical current to a patient's vagus nerve through electrodes placed on the skin for the treatment of headache.

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—EXTERNAL VAGAL NERVE STIMULATOR FOR HEADACHE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction resulting from patient contacting components .. Electrical shock injury from device failure	Biocompatibility evaluation and Labeling. Electrical safety, thermal, and mechanical testing; Software verification, validation, and hazard analysis; and Labeling.
Incorrect stimulation resulting from interference from other electrical devices. Stimulation side effects such as the following	Electromagnetic compatibility testing. Labeling.
<ul style="list-style-type: none"> • Seizure • Cardiac side effects • Worsening of headache. 	
Ineffective therapeutic response due to device failure	Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
User error	Labeling.

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. 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.

At the time of classification, external vagal nerve stimulators for headache are for prescription use only. 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 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

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. 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

the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” 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; 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, 360l, 371.

■ 2. Add § 882.5892 to subpart F to read as follows:

§ 882.5892 External vagal nerve stimulator for headache.

(a) *Identification.* An external vagal nerve stimulator for headache is a prescription device used to apply an electrical current to a patient's vagus nerve through electrodes placed on the skin for the treatment of headache.

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

(1) The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2,000, and 10,000 ohm loads), pulse duration, frequency, net charge (µC) per pulse, maximum phase charge at 500 ohms, maximum current density (mA/cm², r.m.s.), maximum average current (mA), maximum average power density (W/cm²), and the type of impedance monitoring system shall be fully characterized through non-clinical performance testing.

(2) Software verification, validation, and hazard analysis shall be performed.

(3) Biocompatibility evaluation of the patient-contacting components of the device shall be performed.

(4) The device shall be tested for electrical, thermal, and mechanical safety, and for electromagnetic compatibility (EMC).

(5) The labeling must include:

(i) Instructions for proper use of the device, including placement of the device on the patient; and

(ii) Instructions on care and cleaning of the device.

Dated: December 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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