



Food and Drug Administration
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electroCore, LLC
Michael Romaniw
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April 14, 2017

Re: DEN150048
gammaCore Non-invasive Vagus Nerve Stimulator
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 882.8592
Regulation Name: External vagal nerve stimulator for headache
Regulatory Classification: Class II
Product Code: PKR
Dated: October 15, 2015
Received: October 16, 2015

Dear Mr. Romaniw:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the gammaCore Non-invasive Vagus Nerve Stimulator, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

The gammaCore Non-invasive Vagus Nerve Stimulator is intended to provide non-invasive vagus nerve stimulation (nVNS) on the side of the neck. The gammaCore device is indicated for the acute treatment of pain associated with episodic cluster headache in adult patients.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the gammaCore Non-invasive Vagus Nerve Stimulator, and substantially equivalent devices of this generic type, into class II under the generic name, external vagal nerve stimulator for headache.

FDA identifies this generic type of device as:

External vagal nerve stimulator for headache. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a

"not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On October 16, 2015, FDA received your De Novo requesting classification of the gammaCore Non-invasive Vagus Nerve Stimulator into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the gammaCore Non-invasive Vagus Nerve Stimulator into class I or II, it is necessary that the proposed class have sufficient regulatory 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 De Novo request, FDA has determined that the gammaCore Non-invasive Vagus Nerve Stimulator, indicated for the acute treatment of pain associated with episodic cluster headache in adult patients, can be classified in class II with the establishment of special controls. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

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

In combination with the general controls of the FD&C Act, the external vagal nerve stimulator for headache is subject to the following special controls:

1. The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2000, and 10000 ohm loads), pulse duration, frequency, net charge (μC) per pulse, maximum phase charge at 500 ohms, maximum current density (mA/cm^2 , r.m.s.), maximum average current (mA), maximum average power density (W/cm^2), 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:
 - a) Instructions for proper use of the device, including placement of the device on the patient; and
 - b) Instructions on care and cleaning of the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact William Heetderks at 240-402-5360 or William.Heetderks@fda.hhs.gov.

Sincerely,

Angela C. Krueger
Deputy Director,
Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and
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