DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 30, 2017

electroCore, LLC
Mike Romaniw
VP, Quality Assurance & Regulatory Affairs
150 Allen Road, Suite 201
Basking Ridge, New Jersey 07920

Re: K171306
Trade/Device Name: gammaCore-S
Regulation Number: 21 CFR 882.8592
Regulation Name: External Vagal Nerve Stimulator For Headache
Regulatory Class: Class II
Product Code: PKR
Dated: May 2, 2017
Received: May 3, 2017

Dear Mike Romaniw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S
2017.05.30 16:12:38 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
gammaCore-S

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the gammaCore-S 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Applicant: electroCore® LLC
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Date submitted: 02 May 2017

Proprietary Name: gammaCore-S®

Common Name: External vagal nerve stimulator for headache

Classification Status: Class II

Product Codes: PKR

Predicate Device: gammaCore-DEN150048

Device Description: gammaCore-S is a device that provides non-invasive Vagus Nerve Stimulation (nVNS) when applied to the side of the neck. This is a mild electrical stimulation of the vagus nerve, which runs through the neck and carries information to the central nervous system. Each stimulation with gammaCore-S lasts two minutes. The patient controls the stimulation strength.

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

Summary of Technological Characteristics: The gammaCore-S modifications include a change from a thumbwheel control to a two button control for power on/off and control of the stimulation intensity as well as the addition of a small LCD screen which indicates the device status. Additionally, minor software updates were required as a result of these changes.

Summary of Nonclinical Testing: The verification and validation activities, as identified by the risk analysis to ensure that the modified device is as safe and effective as the predicate device, have been completed and demonstrate that the predetermined acceptance criteria have been met.

Additional risks are the same as those submitted in the original submission and have been mitigated in by the same methods. Declarations of Conformity with design controls are provided.

Substantial Equivalence Discussion:

Similarities

The GammaCore-S device technology is identical to the device technology used in the gammaCore. The similarities include:

- Intended use and indication for use:
- Signal Outputs and waveforms
- Materials used for patient contact surfaces
- Power Source

Differences

The differences between the gammaCore-S and the gammaCore can be summarized as "a change in the user interface". The thumb-wheel potentiometer used to turn the gammaCore device on and off, as well as to increase or decrease the treatment signal amplitude, and the single LED that served as a status indicator to the user have been replaced by a pair of buttons, an LCD panel, and an LED. The buttons serve to turn the gammaCore-S on and off, as well as to increase / decrease the treatment signal amplitude. The LCD panel and LED provide device status information to the user.

Summary: The gammaCore-S has the same intended use as the predicate gammaCore device. The gammaCore-S does not alter the fundamental scientific technology of the device because it does not change the operating principle or device output. The modification to the user interface does not impact the device for its intended use in the acute treatment of pain associated with episodic cluster headaches in adult patients.

Clinical Data: Clinical studies were not required to validate the modifications in the gammaCore-S.

Conclusion: The gammaCore-S described in this submission based on the information provided is substantially equivalent to the predicate.