March 30, 2018
ELECTROCORE, LLC
Mike Romaniw
VP, Quality Assurance & Regulatory Affairs
150 Allen Road, Suite 201
Basking Ridge, New Jersey 07920

Re: K180538
Trade/Device Name: gammaCore Sapphire
Regulation Number: 21 CFR 882.8592
Regulation Name: External Vagus Nerve Stimulator for Headache
Regulatory Class: Class II
Product Code: PKR
Dated: February 27, 2018
Received: February 28, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.03.30 08:56:36 -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
Indications for Use

510(k) Number (if known)
K180538

Device Name
gammaCore-Sapphire

Indications for Use (Describe)
The gammaCore Sapphire Non-invasive Vagus Nerve Stimulator is intended to provide noninvasive vagus nerve stimulation (nVNS) on the side of the neck. The gammaCore Sapphire 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 Sapphire 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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Ph: 973-290-0097
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**Establishment Registration Number:** 3009060963

**Contact:** Mike Romaniw
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**Alternate Contact:** Marie Marlow
Chief Executive Officer
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Office: 855-776-0638 x201
Fax: 703-562-9797
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**Date submitted:** February 27, 2018

**Proprietary Name:** gammaCore Sapphire®

**Common Name:** External vagal nerve stimulator for headache

**Classification Status:** Class II

**Product Codes:** PKR
Predicate Device: gammaCore-2 K172270

Device Description: gammaCore Sapphire (gammaCore), like the predicate gammaCore-2 device, is a multi-use, hand-held, rechargeable, portable device consisting of a rechargeable battery, signal generating and amplifying electronics, with a slide control switch for user / operator control of the signal amplitude (relative range 0-40 continuous). Like gammaCore-2, gammaCore Sapphire:

- includes a charging station incorporated into the “clam shell” storage case connected to a power adapter to charge the device as necessary by the end user
- provides visible (light and display) and audible feedback (beep) regarding device and stimulation status
- allows for multiple stimulations or doses. Each stimulation or dose lasts 120 seconds, after which the device automatically turns off, unless turned off earlier by the user / operator

Note: One dose is defined as one stimulation cycle lasting 120 seconds (2 minutes)
- delivers a fixed number of doses within a 24-hour period. Once the maximum daily number of doses has been reached, the device will not deliver any more doses until the following 24-hour period.
- the number of remaining doses available in a 24-hour period is indicated on the Display.

Note: The term "gammaCore-HS" appears in several instances in this submission. The name "gammaCore-HS" was used as a project identifier early in the development process. The name "gammaCore Sapphire" was the final name chosen for the device in preparation for marketing. As such, the names "gammaCore-HS" and "gammaCore Sapphire" refer to the same device in this submission.

In comparison to the gammaCore-2 predicate K172270 (programmed by the manufacturer to deliver 24 doses per day up to a maximum of 99 days), gammaCore Sapphire can be programmed to deliver 24 doses per day for 10, 31, or 93 days and can be refilled / reloaded for additional 10, 31, or 93 day periods via an RFID card encoded and provided by electroCore or its authorized agent.
The device will be provided to the patient/user with an initial 10, 31, or 93-day RFID card based on the healthcare provider's prescription. Additional (refill/reload) cards will be provided in response to a user/patient request based on a prescription from their health care provider. The refill/reload RFID cards will be programmed using the gammaCore Dispensing and Ordering Terminal (gammaCore DOT) by electroCore or its authorized agent. This is a specialized application for dispensing the device therapy.

When a 10, 31, or 93-day refill/reload card is requested by a patient/user (in accordance with a prescription from a healthcare provider) for a specific unique device serial number, an RFID card will be encoded with the appropriate dosage according to the prescription. The encoded RFID card is matched to a specific gammaCore device serial number residing in a database maintained by electroCore. The gammaCore DOT application, running on a Sony Xperia tablet, uses a proprietary encoding algorithm to encrypt the therapy days and doses per day on the refill/reload RFID card, using Near-field Communication (NFC) protocols.

The encoding algorithm is based on a seed-value pair of numbers that are registered in the gammaCore DOT database specific to a device ID (unique device serial number). The gammaCore DOT application ensures that only legitimate seed values allow refilling/reloading of the device by ensuring it can validate the prescription availability and lookup seed value in the gammaCore DOT database based on the unique device ID and patient ID.

The encoded refill/reload RFID card will then be provided to the user/patient that requested the refill/reload of their device, along with one to six additional tubes of conductive gel (number of conductive gel tubes provided is based on the 10, 31, or 93 day refill/reload being provided). On receipt of the RFID card, the user/patient refills/reloads their gammaCore device by placing the RFID card across the face of their device (with the device turned on). The device will display “rd” and the "refill" icon as the device reads the RFID card. The device will signal (beeping twice) when it has been loaded with the programmed doses. The device is now ready to be used for treatment. The RFID card can only be used for one refill/reload; upon completion of the device refill/reload the card may be thrown away.

Additionally, a Bluetooth feature will be enabled to facilitate device diagnostics of any devices returned by patients/users to the manufacturer, to allow a determination of the number of days
the device was used, and/or number of doses, as well as any days / doses yet remaining on a
device. The Bluetooth feature will not be accessible by the patient / user; it is accessible only by
the device manufacturer.

**Intended Use:** The gammaCore Sapphire 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 lasts two minutes. The patient controls the
stimulation strength.

**Summary of Technological Characteristics:** The gammaCore Sapphire modification includes a
change from a pre-programmed device delivering treatment for a range of either 10-days, 31-
days, 93-days, up to 99-days of use to a reloadable / refillable device by use of a RFID card
programmed specifically to a particular device. Minor software updates were required as a result
of this change.

**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 associated with the RFID refill functions have been mitigated. Declarations of
Conformity with design controls are provided.

**Substantial Equivalence Discussion:**

**Similarities**

The GammaCore Sapphire device technology is very similar to the device technology used in the
gammaCore-2 K172270. The similarities include:

- Intended use and indication for use:
- Signal Outputs and waveforms
- Materials used for patient contact surfaces
- Power source
Differences
In comparison to the gammaCore-2 predicate K172270 (programmed by the manufacturer to deliver 24 doses per day up to a maximum of 99 days), gammaCore Sapphire can be programmed to deliver 24 doses per day for 10, 31, or 93 days and can be reloaded/refilled for additional 10, 31, or 93 day periods via an RFID card encoded and provided by electroCore or its authorized agent.

**Summary:** The gammaCore Sapphire has the same intended use as the predicate gammaCore-2 device (K172270). The gammaCore Sapphire 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 available treatment day reload/refill RFID capabilities 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 Sapphire.

**Conclusion:** The gammaCore Sapphire described in this submission based on the information provided is substantially equivalent to the predicate, gammaCore-2 K172270.