January 23, 2018

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

Re: K173442
Trade/Device Name: gammaCore-S
Regulation Number: 21 CFR 882.8592
Regulation Name: External Vagus Nerve Stimulator for Headache
Regulatory Class: Class II
Product Code: PKR, QAK
Dated: November 3, 2017
Received: November 6, 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.

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 -A
2018.01.23 11:04:12 -05'00'

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)*
K173442

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 and migraine 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for the electroCore 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.

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Date of Submission: **03 November 2017**
Proprietary Name: **gammaCore-S®**
Common Name: **External vagal nerve stimulator for headache**
Classification Status: **Class II**
Product Codes: **PKR, QAK**
Predicate Device: **gammaCore-S K171306**

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 and migraine headache in adult patients.

gammaCore-S Device Description: The gammaCore-S device (Catalog # 10009-40601 - gammaCore-S, 31 day, 300 treatment device) is a hand-held portable device consisting of an outer plastic case, a battery, signal generating and amplifying electronics, LED and horn (indicate device status), and a pair of stainless steel skin contact surfaces (referred to as the "stimulation surfaces"). The device operating status is visible on a LCD display screen. Caps are provided to cover the stimulation surfaces when the device is not in use. Conductive electrode gel is provided for use with the device.

The gammaCore-S device produces a low voltage electric signal consisting of five 5000 Hz pulses that are repeated at a rate of 25 Hz. The waveform of the electric pulses is approximately a sine wave with a peak voltage limited to 24 Volts when placed on the skin and a maximum output current of 60mA. The signal is transmitted through the skin of the neck to the vagus nerve. The device allows up to 30 seconds for the operator to position and adjust the stimulation intensity, treatment is intended to be applied for 90 seconds (the treatment automatically stops 120 seconds after the device is powered on). Each device allows for multiple treatments (up to 300 2-minute treatments).

There is no change to the gammaCore-S device as cleared in K171306. The purpose of this submission is for an expanded indication for treatment of pain associated with migraine in adult patients.

Summary of Technological Characteristics: There is no change to the technological characteristics in the gammaCore-S **(**K171306) for this expanded indication.

Summary of Non-Clinical Testing:

There is no change to the technological characteristics in the gammaCore-S (K171306) for this expanded indication; no additional non-clinical or performance testing is required.

Summary of Clinical Data:

Clinical data demonstrating the safety and effectiveness of the gammaCore-S for the treatment of migraine headache was collected from a multicenter, randomized, double-blind, parallel-group, sham-controlled study took place across 10 expert headache centers in Italy from January 11, 2016 through March 31, 2017. The study was designed to compare nVNS to sham treatment and included three 4-week periods. During the study, nVNS was superior to sham in aborting the first treated attack at 30 and 60 minutes but not at 120 minutes (primary end point). A repeated-measures test validated the primary end point, indicating the superiority of nVNS over sham through 120 minutes. Significant benefits of nVNS were also shown across several clinically relevant secondary end points including mild or no pain at 120 minutes, changes in pain intensity from baseline to 60 and 120 minutes, and ≥50% responder (pain free and mild/pain free) rates at 120 minutes. Consistent with previous studies of nVNS for the treatment of primary headache, nVNS was safe and well tolerated.

Substantial Equivalence Discussion:

The gammaCore-S device technology is identical to the device technology used in the gammaCore-S indicated for the acute treatment of pain associated with episodic cluster headache in adult patients. There have been no changes in the technological characteristics nor intended use of the gammaCore-S device for acute treatment of pain associated with migraine headache in adult patients. Due to differences in the characteristics of these two primary headache conditions, there is a difference in the treatment instructions for the device associated with episodic cluster headache versus migraine headache. For both indications, use of more than 8 gammaCore-S treatments per day (for a total of 24 stimulations per day) has not been evaluated and is listed as a precaution in the labeling.

Summary:

The following table summarizes the comparison of the substantial equivalence of the subject device to that of the predicate device.

Table 1. Substantial Equivalence Comparison Table

	gammaCore-S	gammaCore-S	Substantial Equivalence
510(k) number	Subject device	K171306	
Indication for Use	gammaCore-S is indicated for the acute treatment of pain associated with episodic cluster and migraine headache in adult patients.	gammaCore-S is indicated for the acute treatment of pain associated with episodic cluster headaches in adult patients.	Clinical data supports the expanded indication statement. Questions of safety or effectiveness have been addressed in supporting data.
Intended Use	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 lasts two minutes. The patient controls the stimulation strength.	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 lasts two minutes. The patient controls the stimulation strength.	No change in intended use
Rx vs. OTC	Prescription use only	Prescription use only	No change.
Treatment Recommendation	Acute treatment of migraine: 120 second stimulation cycle, 2 bi-lateral stimulations, up to 3 times a day.	Acute treatment of eCH: 120 second stimulation cycle, 3 consecutive stimulations up to 8 times/day.	Change in treatment protocol to reflect different form of primary headache. Supported by clinical data in Section 20 of this submission.
Patient- contacting Materials	SS, ABS-PC, Signagel electrode gel	SS, ABS-PC, Signagel electrode gel	No change in materials
Electrical Classification	UL 60601-1 Class III Type BF Applied Part	UL 60601-1 Class III Type BF Applied Part	No change in classification
Waveform / frequency	Sinusoidal wave, Symmetrical biphasic 5000 Hz pulses at a rate of 25 Hz	Sinusoidal wave, Symmetrical biphasic 5000 Hz pulses at a rate of 25 Hz	No change in waveform or frequency
Maximum output	30V (peak), 60 mA(peak)	30V (peak), 60 mA(peak)	No change in outputs
Load impedance	450-550 Ohms	450-550 Ohms	No change in impedance
Power Supply	3V Lithium battery	3V Lithium battery	No change in power supply voltage
Service Life	1.5 years after manufacture date	1.5 years after manufacture date	No change in service life
Device Circuitry			
Controls	Increase (+) and decrease (-) push buttons	Increase (+) and decrease (-) push buttons	No change in circuitry or controls.

	gammaCore-S	gammaCore-S	Substantial Equivalence
Output regulation	Device software and push buttons	Device software and push buttons	
Device status display	LCD screen	LCD screen	
Electrical Interface Port	For programming software and troubleshooting only; enclosure must be opened for access to the interface port	For programming software and troubleshooting only; enclosure must be opened for access to the interface port	
Optical Port Infrared Connection	Service port intended for manufacturer's access only; receiver only, cannot transmit; shows battery voltage, allows resetting of days and doses.	Service port intended for manufacturer's access only; receiver only, cannot transmit; shows battery voltage, allows resetting of days and doses.	
Audible Signals / Alarms			
Start up	Yes	Yes	No change in available alarm signals.
Session complete	Yes	Yes	
Errors / depleted battery	Yes	Yes	
No doses left	Yes	Yes	
Expired / no days left	Yes	Yes	
Visual Indicators / Display			
Start up (powered on)	Light on	Light on	No change to display/message.
Unit ready (powered on)	Light on / LCD amplitude "0"	Light on / LCD amplitude "0"	
Session complete	Light off / LCD days, doses remaining and last amplitude	Light off / LCD days, doses remaining and last amplitude	
Errors / depleted battery	LCD "Err" / Flashing Light	LCD "Err" / Flashing Light	
No doses left	Flashing light / LCD # doses remaining	Flashing light / LCD # doses remaining	
Expired / no days left	Flashing light / LCD days remaining	Flashing light / LCD days remaining	
Low battery	No light / LCD Display "Lo"	No light / LCD Display "Lo"	

Conclusion:

There have been no changes in the technological characteristics nor intended use of the gammaCore-S device for acute treatment of pain associated with migraine headache in adult patients. The addition of migraine headache to the indications for use does not raise new or different questions of safety or effectiveness compared to that of the predicate device. Therefore,

the presented information demonstrates that the subject device is substantially equivalent to the predicate device.