October 26, 2022

Neurent Medical
Karen Peterson
Vice President Clinical, Regulatory & Quality
1 Oran Point, Main Street, Oranmore
Galway, Connaught H91D7X2
Ireland

Re: K222032
Trade/Device Name: NEUROMARK System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 28, 2022
Received: July 29, 2022

Dear Karen Peterson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222032

Device Name
NEUROMARK® System

Indications for Use *(Describe)*
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

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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510(K) SUMMARY

Date Prepared: Oct 20, 2022

Submitter Information:
Neurent Medical
1 Oran Point, Main Street
Oranmore, Co. Galway, H91 D7X2
Ireland

Establishment Registration: 3016813690

Contact Information:
Karen E. Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
(651) 398-4341
karen@neurentmedical.com

Device Information:

Trade Name:	NEUROMARK® System [K222032]
Common Name:	Radiofrequency Probe
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	GEI
Classification:	Class II
Regulation Number:	21 CFR 878.4400
Predicate Device:	NEUROMARK® System [K212666]

Device Description:
The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis.

The NEUROMARK® System is composed of the NEUROMARK® Device and the NEUROMARK® Radiofrequency (RF) Console.

The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft, and treatment tip. The treatment tip, which is referred to as the End Effector, consists of an array of bipolar electrodes that deliver RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft of the device is pre-shaped to aid access and delivery to the nasal cavity but is malleable to allow the user to bend or shape it to accommodate variations in anatomy to access the desired treatment area. The NEUROMARK® Device is operated via handle, slider and activation button. Once in the desired position within the nasal cavity, the operator moves the slider backwards which retracts the outer sheath, deploying the End Effector. Using the activation button, the user initiates a bio-impedance check to assess and confirm contact between the End Effector and the treatment area. Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle. The NEUROMARK® Device is intended for single use and provided sterile (EO).

The NEUROMARK® Device is designed for use with the NEUROMARK® Radiofrequency (RF) Console; it includes features to allow compatibility and authentication once connected, via a flexible interface cable, to the Console.

The NEUROMARK® Console delivers, monitors and controls RF energy to the Device. The Console is mounted on an ergonomic mobile stand for ease of use. The Console includes a Graphical User Interface (GUI) which provides operational instructions for the procedure, directs the user to select nasal cavities for treatment, indicates when the device is in contact with tissue and ready to start treatment, provides status of therapy and indicates when the procedure is complete. The NEUROMARK® Console works in conjunction with software.

Indication for Use:
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

Technological Characteristics:
The NEUROMARK® System (subject device) has the same indications for use and fundamental scientific technology as the predicate NEUROMARK® System [K212666].

The subject device has the same technological characteristics (i.e., principle of operation, basic design, functionality, energy type, biocompatibility, sterile packaging, shelf life, and sterilization) as the predicate device. The Treatment Tip (End Effector) of the subject device has different material and base component construction from that of the predicate device. The subject device has electrodes distributed over 4 proximal leaflets compared to 6 proximal leaflets in the predicate device. In addition, the subject device connector and interface cable was modified to simplify the connection of the device to interface cable.

Substantial Equivalence:
The NEUROMARK® System has the same indications for use and fundamental scientific technology as the predicate device. Evaluation of the impact of the device modifications was completed. No new risks were identified and relevant performance testing was repeated to ensure the subject device still meets intended use, product specifications, and performs similarly to the predicate device.

Performance Data:
Performance testing of the NEUROMARK® System consisted of design verification/validation testing, biocompatibility, software, and electrical and thermal safety testing to support the device modifications listed above. All testing passed and showed that the device meets design specifications and performed as intended.

Conclusion:
In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the subject device is as safe and effective and is substantially equivalent to the predicate device.