October 22, 2021

Neurent Medical
Kenny Walsh
QA/RA Manager
1 Oran Point, Main Street, Oranmore
Galway, Galway H91D7X2
Ireland

Re: K212666
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: August 13, 2021
Received: August 23, 2021

Dear Kenny Walsh:

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 of 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)*
K212666

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

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92

Submitter Information

Submitter	Neurent Medical 1 Oran Point, Main Street, Oranmore, Co. Galway Ireland
Primary Contact Person	Kenny Walsh, Quality & Regulatory Affairs Manager, Neurent Medical Phone: +353 91 470720
Date Prepared	21 October 2021

Device Information

Proprietary Name	**NEUROMARK™ System**
Common Name	Radiofrequency Probe
Classification Name	Electrosurgical cutting and coagulation device and accessories
Classification Panel	General and Plastic Surgery
Device Class	Class II
Product Code	GEI
CFR Section	21 CFR 878.4400
Predicate Device	Aerin Medical RHIN1 Stylus (K192471)
Reference Device	Polaris RF Ablation System (K181864)

Device Description

The NEUROMARK™ System is intended for the application of Radiofrequency 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™ Device is a handheld bipolar radiofrequency device which is designed for use in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures along with the NEUROMARK™ Generator.

The NEUROMARK™ System comprises of two key elements which are described in this section:

1. The NEUROMARK™ Device and
2. The NEUROMARK™ Generator

The NEUROMARK™ Device is a hand-held single-use bi-polar 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 micro electrodes. These electrodes deliver bipolar RF energy while monitoring feedback on the tissue bio-impedance changes allowing for controlled RF energy level delivery. The shaft of the device is pre-shaped for optimal access and delivery to the nasal cavity but is malleable to allow the user to bend or shape the shaft to accommodate variations in anatomy to access the desired treatment area(s). The NEUROMARK™ Device is operated via handle, slider and activation switch. Once in the desired position within the nasal cavity, the operator moves the slider backwards which retracts the outer sheath, deploying the end effector array. Using the switch, the user initiates a bio-impedance check, to assesses and confirm contact between the end effector and the treatment area. Once the system confirms contact has been achieved, a subsequent press of the button initiates the RF delivery cycle.

The NEUROMARK™ Device is designed for use with the NEUROMARK™ Radiofrequency Generator; it includes features to allow compatibility and authentication once connected, via a flexible cable, to the NEUROMARK™ Radiofrequency Generator. The NEUROMARK™ Radiofrequency Generator delivers, monitors and controls RF energy to the device. The generator meets the following requirements: RF operating frequency of 460 – 480 kHz (± 5 kHz); bipolar low power energy delivery and feedback control with low overshoot capabilities.

The NEUROMARK™ Device is intended for single use and provided sterile (EtO). The NEUROMARK™ Radiofrequency Generator is mounted on an ergonomic mobile stand for ease of use. The Graphical User Interface (GUI) provides operational instructions for the procedure; directs user to select nasal cavities for treatment, indicates when the device is apposed and primed to start treatment, provides status of therapy and indicates when the procedure is complete. The NEUROMARK™ Radiofrequency Generator works in conjunction with software.

The subject device and predicate device have similar technological characteristics. The primary differences relate to the geometry of the electrode array and the method of controlling power delivery (bioimpedance control for the subject device versus temperature control for the predicate device).

Indications 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.

Comparison of Technological Characteristics with Predicate Device

Application of radiofrequency energy to create lesions in tissue by coagulation necrosis is the technological principle for both the subject and predicate devices. This is based on the use of a surface contacting electrode array device, connected to an RF generator to apply RF energy to mucosal tissue. At a high level, the NEUROMARK™ and the predicate have the following same technological elements:

- Class II; GEI; 21 CFR 878.4400; Electrosurgical, Cutting & Coagulation & Accessories.
- Single use and sterile device (EtO).

- Device design comprises a handle, malleable shaft and treatment tip with bipolar electrodes, radiofrequency generator.
- Device materials are standard medical grade materials - no materials of animal origin or nanotechnology.
- Device inserted via the nostrils - target location is the nasal cavity in the area of the posterior nasal nerves.
- Energy delivery:
    - Same energy type (bi-polar RF energy).
    - Same energy operating range.
    - Same energy delivery contact site.
    - Same energy delivery mechanism (via a surface contacting electrode array).

Performance Data Summary

The following performance data was completed to support the substantial equivalence determination.

- Bench Testing was completed to ensure that the device design is capable of meeting performance specifications, thereby ensuring the safety and effectiveness of the device. Bench Testing included:
    - Dimensional Testing
    - Deployment/Constrainment Testing
    - Tensile Testing
    - Device Integrity Testing
    - Electrical Continuity and Isolation Testing
    - Packaging Integrity Testing
- Biocompatibility Testing

  The biocompatibility evaluation for the NEUROMARK™ System was conducted in accordance with ISO 10993-1: 2018 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process' (FDA Recognition Number 2-258) and in consideration of FDA Guidance document 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

  The testing conducted included the following tests:

    - Cytotoxicity
    - Acute Systemic Toxicity
    - Intracutaneous Irritation
    - Material Mediated Pyrogenicity
    - Sensitization

The NEUROMARK™ System is categorized as an externally communicating device in limited contact (≤ 24 hours) with tissues of patients.

- Electromagnetic Compatibility Testing (IEC 60601-1-2)

  Electromagnetic Compatibility Testing was conducted on the NEUROMARK™ System. The NEUROMARK™ System complies with the IEC 60601-1-2 standard for Electromagnetic Compatibility.

- Electrical Safety Testing (IEC 60601-1, IEC 60601-2-2)

  Electrical Safety Testing was conducted on the NEUROMARK™ System. The NEUROMARK™ System complies with the IEC 60601-1 and IEC 60601-2-2 standards for Electrical Safety.

- Characterization of Thermally Affected Zones

  Thermal performance was assessed using *ex-vivo* experimentation and supported by computational analysis. Thermal performance of the NEUROMARK™ System was comparable with the predicate device.

- Human Factors Evaluations

  Human Factors Evaluations was conducted on the NEUROMARK™ System. The NEUROMARK™ System complies with the IEC 62366 and the evaluations were conducted in consideration of FDA Guidance document "Applying Human Factors and Usability Engineering to Medical Devices".

  An early feasibility Clinical Study was conducted to evaluate the NEUROMARK System's usability and procedure logistics on healthy volunteers. The successful completion of the study, including device delivery, deployment and positioning of the device under endoscopic guidance, with no adverse events, confirms the appropriateness of the NEUROMARK™ System for therapeutic clinical applications.

- Software Verification and Validation Testing

  Software verification and validation testing were conducted and documentation was provided as recommended by FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for the NEUROMARK System was considered as a "major" level of concern since a failure could result in serious injury.

Clinical Tests

Clinical testing of the NEUROMARK™ System included a feasibility study. The RELIEVE feasibility study is a safety and technical feasibility study of eleven (11) patients (RELIEVE Study).

The RELIEVE study is a prospective, single-arm (non-randomized), bilateral safety and technical feasibility evaluation of the NEUROMARK™ System in patients with chronic rhinitis. Eleven (11) adults (>18 years) with chronic rhinitis, (allergic or nonallergic) presenting with rhinorrhoea and/or congestion symptoms (≥2 reflected Total Nasal Symptom Score sub-scale) were enrolled. The

device was used to create radiofrequency (RF) lesions to disrupt posterior nasal nerves. The study was conducted in the United States under an IRB approved study.

Primary Safety Endpoint:

Safety was assessed based on device-related serious adverse events reported up to 1-month post-procedure.

Primary Technical Feasibility Endpoint:

Technical feasibility was assessed based on the ability of the NEUROMARK™ System to access the naval cavity and deliver energy to the target treatment areas.

Safety Results:

The procedure was successfully completed in all twenty-two (22) nasal cavities (100%) of patients, with no serious adverse events, adverse events or complications. The primary safety endpoint was met.

Technical Feasibility Results:

Access to the nasal cavity and delivery of energy to the target treatment areas in 22 nasal cavities (100%) was completed. The primary technical feasibility endpoint was met.

Additional Evaluations:

The procedure was well tolerated with a 100% positive responder rate at 6-months post index (subjects with at least one rTNSS class improvement). Population baseline rTNSS (total nasal symptom score) was 8/15. At the 6-month follow up, population rTNSS had reduced to 4/15.

Discomfort and/or Pain levels were low and resolved immediately post procedure.

Summary:

This study provides initial data that the NEUROMARK™ procedure is safe and technically feasible. Additional evaluations indicate that the procedure is well tolerated and results in similar improvement in symptoms to that of the predicate.

Conclusion

The NEUROMARK™ System has been shown to be substantially equivalent to the predicate device based on Indications for Use, Principles of Operation and Technological Characteristics. The non-clinical data and thermal safety data support substantial equivalence of the NEUROMARK™ System with the predicate device and the software verification and validation demonstrate that the NEUROMARK™ System should perform as intended in the specified use conditions. The clinical data provides additional confirmation of safety reporting no adverse events and indicates similar symptomatic improvement. The NEUROMARK™ System is as safe, as effective, and performs as well as the predicate device that is currently marketed for the same intended use.