



June 16, 2026

Neurent Medical , Ltd.
Fay Dalton
Senior Regulatory Affairs Specialist
Oranpoint, Main St., Oranmore
Galway, H91 D7X2
Ireland

Re: K261833

Trade/Device Name: NEUROMARK System (NMK00301)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 2, 2026
Received: June 2, 2026

Dear Fay Dalton:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SHUCHEN PENG -S

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

Indications for Use

510(k) Number (if known)
K261833

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 through destruction of soft tissue 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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Neurent Medical

510(k) Summary

Date Prepared: June 2, 2026

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Contact Information: Fay Dalton
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Device Information:

Trade Name: NEUROMARK System
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 [K250048]

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 only and is connected via a flexible interface cable.

The NEUROMARK Console delivers, monitors and controls RF energy to the Device. 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 through destruction of soft tissue to disrupt posterior nasal nerves in patients with chronic rhinitis.

Technological Characteristics:

The subject NEUROMARK System is identical to the predicate NEUROMARK System [K250048] with respect to all technological characteristics, including but not limited to:

- Fundamental scientific technology and principle of operation;
- Anatomical location of use;
- Device design and configuration;
- Energy type, waveform, frequency, and maximum power output;
- Feedback control mechanism;
- Thermal lesion characteristics and thermal safety;
- Software, electrical safety, and electromagnetic compatibility;
- Patient-contacting materials and biocompatibility;
- Sterilization method, sterile barrier packaging, and shelf-life.

There are no new or modified technological characteristics of the subject device in comparison to those of the predicate device [K250048].

Performance Data:

The modification is limited to clarification of the indications for use only and does not affect device design, performance, or technological characteristics. Accordingly, no new performance data were required.

Previously submitted verification and validation data remain applicable and continue to demonstrate that the device meets all acceptance criteria and supports a determination of substantial equivalence to the predicate device.

Substantial Equivalence:

The NEUROMARK System has the same intended use and fundamental scientific technology as the predicate device. An evaluation of the impact of the modification was conducted and confirmed that the change to the indications for use does not affect the device design, performance characteristics, or risk profile, and does not raise different questions of safety and effectiveness. As no changes impacting device performance were implemented, no new performance testing was required; previously submitted verification and validation data remain applicable and continue to demonstrate that the device meets its specifications and intended use. The NEUROMARK System is substantially equivalent to the predicate device.

Conclusion:

In conclusion, the intended use and fundamental technological characteristics are the same as the predicate device. No new performance testing was required, and previously submitted data remain applicable. Accordingly, the device is as safe and effective as the predicate device and is substantially equivalent.