August 15, 2025

NeuroOne Medical Technologies Corp.
Debra Kridner
Regulatory Consultant
7599 Anagram Drive
Eden Prairie, Minnesota 55344

Re: K251243
Trade/Device Name: OneRF Trigeminal Nerve Radiofrequency Probes
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: July 16, 2025
Received: July 17, 2025

Dear Debra Kridner:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2025.08.15 11:23:07 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251243

Device Name
NeuroOne OneRF Trigeminal Nerve Radiofrequency (TN-RF) Probe

Indications for Use *(Describe)*
The NeuroOne OneRF Trigeminal Nerve Ablation System is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures.

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 summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:	K251243
Date Prepared:	August 15, 2025
Applicant:	NeuroOne Medical Technologies Corp. 7599 Anagram Drive Eden Prairie, MN 55344 Phone: (952) 426-1383 E-mail: debk@nmtc1.com
Contact Person:	Debra Kridner Regulatory Affairs Consultant 7599 Anagram Drive Eden Prairie, MN 55344

SUBJECT DEVICE

Trade/Device Name:	NeuroOne OneRF® Trigeminal Nerve Radiofrequency (TN-RF) Probe
Device Regulation Number:	21 CFR§882.4725
Device/Regulation Name:	Radiofrequency lesion probe
Product Code:	GXI
Device Class/ Regulation Classification:	Class II

DEVICE DESCRIPTION (For the Device Subject to this 510(k) Premarket Notification)

OneRF® Trigeminal Nerve Ablation System

OneRF® Ablation System for Trigeminal Nerve (TN) Ablation uses radiofrequency (RF) ablation to create lesion(s) in an area of nerve tissue that the surgeon has identified for ablation. The ablation site may be identified by diagnostic stimulation of the trigeminal nerve using the Trigeminal Nerve Radiofrequency (TN-RF) Probe to accurately locate the target area for ablation.

The subject device is identical to the sEEG-RF Probe cleared after FDA review of K231675. In K231675, the FDA reviewed and cleared the sEEG-RF Probe when used with the NeuroOne OneRF® Generator to form the OneRF® Ablation System. The OneRF® Ablation System is indicated to create radiofrequency lesions in nervous tissue for functional neurosurgical procedures.

In this new 510(k), we propose to market the identical sEEG-RF Probes to create lesion(s) in the trigeminal nerve "for the treatment of pain." This use for treatment of facial pain requires new accessories (Cannula and Tuohy Borst Adapter) for insertion/placement of the sEEG-RF Probe. When the sEEG-RF Probe is used to create lesion(s) in the trigeminal nerve, it will be marketed as the Trigeminal Nerve Radiofrequency (TN-RF) Probe. The TN-RF Probe and new accessories, when combined with the cleared (K231675) NeuroOne OneRF® Generator and accessories, will be referred to as the OneRF® Trigeminal Nerve Ablation System.

Figure 1 displays the components of the OneRF® Trigeminal Nerve Ablation System. All

components in blue and light blue are identical to those cleared in the OneRF® Ablation System (K231675). The only difference between the components is the addition of new accessories in orange (Cannula and Tuohy Borst Adapter) for insertion/placement of the TN-RF Probe (i.e., sEEG-RF Probe).

The OneRF® for TN Ablation System components/accessories consist of the following:

1. **TN-RF Probe** (with Stylet)
   - 16mm x 5 Contact TN-RF Probe Kit
   - 26.5mm x 8 Contact TN-RF Probe Kit
2. **Insertion Components**
   i. Insulated Cannula w/Stylet
   ii. Tuohy Borst Adapter (Adapter)
3. **Stimulation Components**
   i. Cable Assembly (5 or 8 connector pins) (CA)
4. **Ablation Components**
   i. Stylet
   ii. Temperature Accessory (TA)
   iii. Spacer Tubes
   iv. Radiofrequency Connector Box (RFCB)
   v. Equipment
      1. Generator
      2. Generator Interface Cable (GIC)
      3. Cart
      4. Foot Pedal (optional)
      5. Ground Pad

PREDICATE DEVICE (S)

The primary predicate is the Cosman TEW Trigeminal Nerve RF Probe which received marketing authorization after FDA review and clearance of K050084 under 21 CFR 882.4725 (product code GXI). This RF Probe was chosen as the primary predicate because it has the same intended use/indications for use, namely RF lesioning of the nerve tissue (trigeminal ganglion) for treatment of pain and similar technological characteristics as the subject RF Probe.

A second predicate is the NeuroOne sEEG-RF Probe which received marketing authorization after FDA review and clearance of K231675) under 21 CFR 882.4725 (product code GXI). This RF Probe was chosen as the secondary predicate because it has the same intended use and technological characteristics as the subject RF Probe. The identical sEEG-RF Probes are being used to support a this use to create lesion(s) in the trigeminal nerve "for the treatment of pain." This new indication for treatment of facial pain requires new accessories (Cannula and Tuohy Borst Adapter) for insertion/placement of the sEEG-RF Probe. When the sEEG-RF Probe is used to create lesion(s) in the trigeminal nerve, it is marketed as the Trigeminal Nerve Radiofrequency (TN-RF) Probe. The TN-RF Probe and new accessories, when combined with the cleared (K231675) NeuroOne OneRF® Generator and accessories, will be referred to as the OneRF® Trigeminal Nerve Ablation System.

The predicate devices were chosen as the Intended Use is the same. The Indications for Use, Fundamental Scientific Technology, and Principles of Operation are either the same or if different did not raise new questions of safety and/or effectiveness when compared to the subject device.

INDICATIONS FOR USE

The NeuroOne OneRF® Trigeminal Nerve Ablation System is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures.

COMPARISON OF SUBJECT DEVICE TO PRIMARY PREDICATE DEVICE And PREDICATE DEVICE

Device Classification Comparison - RF Probe				
	Subject Device (TN-RF Probe) K251243	**Primary Predicate Device Cosman TEW-RF Probe K050084**	**Predicate Device sEEG-RF Probe K231675**	**Comparison Same/Different**
Device Regulation Number:	21 CFR§882.4725	21 CFR§882.4725	21 CFR§882.4725	**Same for All**
Device / Regulation Name:	Radiofrequency lesion probe	Radiofrequency lesion probe	Radiofrequency lesion probe	**Same for All**
Device Regulation Identification:	A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.	A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.	A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired	**Same for All**
Product Codes:	GXI [Probe, Radiofrequency Lesion]	GXI [Probe, Radiofrequency Lesion]	GXI [Probe, Radiofrequency Lesion]	**Same for All**
Device Class / Regulation Classification:	Class II	Class II	Class II	**Same for All**

Intended Use/Indications for Use Comparison – RF Probe				
	Subject Device (TN-RF Probe) K#_____	**Primary Predicate TEW RF Probe K050084**	**Predicate Device sEEG-RF Probe K231675**	**Comparison Same/Different**
Intended Use:	To be connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired	To be connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired	To be connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired	**Same for ALL**
Indications for Use:	The NeuroOne OneRF® Trigeminal Nerve Ablation System is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures.	"The Cosman Radiofrequency Lesion Generator, Model RFG-1A, and associated Radiofrequency Lesion Probes, is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures."	"The NeuroOne OneRF Radiofrequency Ablation System is indicated for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures"	**Same as Primary Predicate Device**

Technological and Performance Characteristics Comparison - RF Probe				
	Subject Device TN-RF Probe K#_____	**Primary Predicate Device TEW RF Probe K050084**	**Predicate Device sEEG-RF Probe K231675**	**Comparison Identical /Different**
RF Probe Configuration	Single open lumen probe (closed at tip)	Single closed lumen probe	Single open lumen probe (closed at tip)	**Different to Primary Predicate; Identical to sEEG-RF Probe**
Temperature Measurement Capabilities	Yes	Yes	Yes	**Identical**
Location of Temperature Sensor	On Temperature Accessory (inserted into lumen of probe)	Embedded in probe tip	On Temperature Accessory (inserted into lumen of probe)	**Different to Primary Predicate; Identical to sEEG-RF Probe**
Patient- Contact Materials: RF Probe	Polyimide - electrode Platinum - contact	Stainless steel Insulation – (medical grade, abrasion resistant)	Polyimide - electrode Platinum - contact	**Different to Primary Predicate; Identical to sEEG-RF Probe**
Patient- Contact Materials: Cannula	Stainless steel Insulated	Stainless steel Insulated	No Cannula	**Identical to Primary Predicate No corresponding cannula for sEEG-RF Probe**
Compatibility with RF Generator	Yes	Yes	Yes	**Identical**
Key Dimensions:				
Electrode Contact Active Length	2 mm	≤ 5 mm	2 mm	**Different to Primary Predicate;**

				Identical to sEEG-RF Probe
RF Probe Diameter	0.8 mm	0.8 mm	0.8 mm	**Identical**
Number of Contacts	5 to 8 contacts on each probe able to perform Ablation	1 contact on each probe tip able to perform Ablation	4 to 15 contacts on each probe able to perform Ablation	**Different to Primary Predicate;** **Different to sEEG-RF Probe**
Create Lesions in Nerve/Nervous Tissue	Yes	Yes	Yes	**Identical**
Lesion Size Test Method in Ex-vivo Tissue	Yes	Yes	Yes	**Identical**
Insertion Cannula OD (gauge)	18g	19g	No Cannula	**Different**

System Characteristics	
System Characteristic	**Identification**
User	Neurosurgeons familiar with RF lesion techniques
Anatomical Site of Use	Nerve tissue
Access Method	Cannula inserted through foramen ovale and RF Probe passed through the inner lumen of the cannula to the Trigeminal ganglion
Energy Type	Radiofrequency
Procedure Type	Ablation
Principles of Operation	Operator controlled; RF delivered from RF generator to compatible TN - RF probes
Mechanism of Action	Cellular necrosis through thermal coagulation
System Feedback Mechanism	Temperature controlled
Ability to Make Multiple Lesions	Yes

SUMMARY OF PERFORMANCE TESTING AND STANDARDS

The following performance data were provided in support of the substantial equivalence determination for the subject device, Trigeminal Nerve RF Probe with probe insertion/placement accessories (e.g., Cannula and Tuohy Borst Adapter) as individual components and together as an RF Ablation System. to the primary predicate TEW RF Probe (Cosman). Performance testing of the subject device was conducted to demonstrate that the device meets its performance specifications. Results of design verification and validation activities did not raise any new or different questions of safety or effectiveness. The risk management process was used throughout the non-clinical verification activities in accordance with ISO 14971. The following tests/analysis were conducted.

Non-Clinical Performance Tests		
Test	**Overview Summary**	**Results and Conclusions**
Lesion Size Testing	This testing was performed to provide a measurement of the size of the lesion as a function of temperature and time, for each configuration (monopolar, bipolar), and mode (temperature control, manual).	Lesion sizes were proportional to time and temperature. Lesion size is comparable to predicate.
Dimensional Verification of the Cannula	This testing was performed to evaluate the dimensional characteristics and to demonstrate compatibility between components.	Pass – The test results indicate that the Cannula meet the dimensional requirements.
Mechanical Performance	This testing was performed to verify specifications related to the mechanical interaction between the TN-RF Probe, Cannula and Tuohy Borst Adapter.	Pass – The test results indicate that the TN-RF Probe, Cannula, Tuohy Borst Adapter designs meet the mechanical performance requirements
Mechanical Integrity	This testing was performed to evaluate the mechanical integrity of the TN-RF Probe, Cannula and Tuohy Borst Adapter.	Pass - The test results indicate that the TN-RF Probe, Cannula and Tuohy Borst Adapter designs meet the mechanical integrity requirements
TN-RF Probe Kit (TN-RF Probe, Cannula w/stylet and Tuohy Borst Adapter) Package Integrity	The packaged device and labeling shall withstand the conditions of packaging, shelf life, and distribution testing to ISO 11607-1, ISTA 3A, ASTM D4169, ASTM F1980, ASTM F2096, ASTM F88 without loss of function, sterility, or legibility.	Pass - The test results indicate that the TN-RF Probe Kit (TN-RF Probe, Cannula w/stylet, Tuohy Borst Adapter) packaging designs meet the integrity requirements (i.e., seal strength, bubble leak, label inspection, and no damage that impacts device sterility).

Sterilization	The sterilization process shall be validated to demonstrate a minimum of SAL of 10^{-6} for the product using Ethylene Oxide per ISO 11135	Pass – All criteria passed and the new product/package configuration was adopted into the validated sterilization cycle.
Usability – Summative Validation	This testing was performed in accordance with FDA guidance, "*Applying Human Factors and Usability Engineering to Medical Devices*," February 3, 2016	Pass – The NeuroOne OneRF® TN-RF Ablation System has been found to be safe and effective for the intended users, uses, and use environments.

Biocompatibility	
Biocompatibility Overview	**Conclusions**
Components tested: sEEG-RF Probe prolonged (>24 hours to 30 days) contact with tissue/bone.	Passed – Reference (K211367/K222404)
Components tested: Cannula w/stylet, Tuohy Borst Adapter with limited (≤24 hours) tissue	Passed
OneRF® Ablation System Sterile Components: Temperature Accessory/Spacer Tubes/Stylet and Radio Frequency Connector Box	No testing - there is No direct or indirect patient contact

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device and primary predicate device have the same Intended Use/Indications for Use, Device Regulation Number/Name/Identification and Product Codes. The differences in the Fundamental Scientific Technology between the subject device, Trigeminal Nerve Radiofrequency (TN-RF) Probe and the primary predicate Cosman Medical TEW RF Probe do not raise new questions regarding safety and effectiveness when compared. Conclusions drawn from the nonclinical testing demonstrate the device is as safe, as effective, and performs as well as the legally marketed device predicates, per 21 CFR 807.92(b)(3).