December 6, 2023

NeuroOne Medical Technologies Corp.
% John Doucet, Ph.D.
Vice President, Regulatory Affairs - Neuromodulation and Evolving Technologies
MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, District of Columbia 20001

Re: K231675
Trade/Device Name: OneRF Ablation System
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD, GXI
Dated: November 6, 2023
Received: November 6, 2023

Dear Dr. John Doucet:

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.

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: 2023.12.06 15:41:45 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*

K231675

Device Name

NeuroOne OneRF Radiofrequency Ablation System

Indications for Use *(Describe)*

The NeuroOne OneRF Radiofrequency Ablation System is indicated for creation of radiofrequency lesions in nervous 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
# K231675

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:** | K231675 |
| **Date Prepared:** | December 6, 2023 |
| **Applicant:** | NeuroOne Medical Technologies Corp.<br>7599 Anagram Drive<br>Eden Prairie, MN 55344<br>Phone: (952) 426-1383<br>E-mail: debk@nmtc1.com |
| **Contact Person:** | Debra Kridner<br>Regulatory Affairs Consultant<br>7599 Anagram Drive<br>Eden Prairie, MN 55344 |

## SUBJECT DEVICE

| | |
|---|---|
| **Trade/Device Name:** | OneRF™ Ablation System |
| **Device Regulation Number:** | 21 CFR§882.4400<br>21 CFR§882.4725 |
| **Device/Regulation Name:** | Radiofrequency Lesion Generator, Radiofrequency Lesion Probe |
| **Product Code:** | GXD<br>GXI |
| **Device Class/ Regulation Classification:** | Class II |

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

**OneRF™ Ablation System**

The OneRF™ Ablation System components consist of the:

1. **Radiofrequency (RF) Generator** and Accessories
   a. Generator Interface Cable (GIC), Cart and Foot Pedal (optional)
2. **sEEG-RF Probe** (with Universal Cable Assembly) and Ablation Accessories
   a. Temperature Accessory, Spacer Tubes, Stylet and RF Connector Box

The OneRF™ Ablation System uses radiofrequency ablation to create lesion (s) in an area of nervous tissue that the neurosurgeon has identified for ablation. This is accomplished by diagnostically locating the area to ablate using the implanted Stereoelectroencephalography (sEEG). Once the area of ablation is located, the generator and ablation accessories are taken to the patient with implanted sEEG(s). The sEEG(s) now function as an sEEG-RF Probe for RF ablation.

To perform the ablation the Temperature Accessory (TA) is inserted into the sEEG-RF Probe to the predetermined electrode contact location using the specified spacer tube. A stylet may be used to ensure the lumen is patent prior to inserting the TA. The universal cable assembly remains attached to the sEEG-RF Probe while its cables are disconnected from the diagnostic head box. One (monopolar) or two (bipolar) cables from the universal cable assembly are inserted into the radiofrequency connector box (RFCB) depending on the contact area(s) to be ablated. The TA is also connected to the RFCB. The RFCB is attached to the Generator Interface Cable which is attached to the Generator. Temperature and time are used to create lesion (s).

## PREDICATE DEVICE

NeuroOne has chosen a Radiofrequency Lesion Generator as our primary predicate device; specifically, the Cosman G4 Radiofrequency Generator that received marketing authorization after FDA review of K082051 and was cleared under 21 CFR 882.4400 (product code GXD). This RF Generator was chosen as the primary predicate because it has the same intended use, namely lesioning nervous tissue for neurosurgical procedures and similar technological characteristics as the subject device generator.

A second predicate device Radiofrequency Lesion Probe was chosen as RF lesions can only be created with a RF Generator and RF Probe. This device is the Diros OWL RF Probe which received marketing authorization after FDA review of K010202 and was cleared under 21 CFR 882.4725 (product code GXI). To create an RF Ablation System this RF Probe was chosen as an additional predicate because it has the same intended use as NeuroOne's sEEG-RF Probe; namely, to be connected to an RF Generator for lesioning nervous tissue for neurosurgical procedures and similar technological characteristics as the subject device probe.

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 Radiofrequency Ablation System is indicated for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures.

## COMPARISON OF SUBJECT DEVICE (SYSTEM) TO PRIMARY PREDICATE DEVICE (RF GENERATOR) and PREDICATE (RF PROBE)

### DEVICE CLASSIFICATION COMPARISON – RF GENERATOR AND RF PROBE

| **Device Classification Comparison - Generator** | | | |
|---|---|---|---|
| | **Subject Device** | **Primary Predicate Device K082051** | **Comparison Same/Different** |
| **Trade/Device Name:** | NeuroOne OneRF™ Ablation System Generator | Cosman RF Generator | **NA** |
| **Device Regulation Number** | 21 CFR§882.4400 | 21 CFR§882.4400 | **Same** |
| **Device / Regulation Name** | Radiofrequency lesion generator | Radiofrequency lesion generator | **Same** |
| **Device Regulation Identification** | A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites. | A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites. | **Same** |
| **Product Codes** | GXD | GXD | **Same** |
| **Device Class / Regulation Classification** | Class II | Class II | **Same** |

| **Device Classification Comparison - Probe** | | | |
|---|---|---|---|
| | **Subject Device** | **Predicate Device K010202** | **Comparison Same/Different** |
| **Trade/Device Name:** | NeuroOne OneRF™ Ablation System sEEG-RF Probe | Diros RF Probe | **NA** |
| **Device Regulation Number** | 21 CFR§882.4725 | 21 CFR§882.4725 | **Same** |
| **Device / Regulation Name:** | Radiofrequency lesion probe | Radiofrequency lesion probe | **Same** |
| **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. | **Same** |
| **Product Codes** | GXI | GXI | **Same** |
| **Device Class / Regulation Classification** | Class II | Class II | **Same** |

## INTENDED USE/INDICATIONS FOR USE COMPARISON TABLE – RF GENERATOR/RF PROBE (ABLATION SYSTEM)

| **Intended Use/Indications for Use Comparison RF Generator and RF Probe (Ablation System)** | | | |
|---|---|---|---|
| | **Subject Device (RF Ablation System) K231675** | **Primary Predicate RF Generator K082051 and Predicate RF Probe K010202** | **Comparison Same/Different** |
| **Intended Use** | RF Ablation System consists of a generator and probe used for lesioning nervous tissue for neurosurgical procedures. | RF Ablation System consists of a generator and probe used for lesioning nervous tissue for neurosurgical procedures. | **Same** |
| **Indications for Use** | The NeuroOne OneRF™ Radiofrequency Ablation System is indicated for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures. | **RF Generator**<br>The Cosman G4 Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures.<br>*The Cosman G4 Radiofrequency Generator is used with separately approved Cosman Radiofrequency Probes*<br>**RF Probe**<br>1. Lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies;<br>or<br>2. radiofrequency heat lesion procedures for the relief of pain | **Different**<br>Removed reference to relief/treatment of pain.<br><br>The subject device indications for use does not separately define a specific probe or generator as they are defined as part of the NeuroOne system. |

## TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS COMPARISON

| Technological and Performance Characteristics Comparison – RF Generator | | | |
|---|---|---|---|
| | **Subject Device** | **Primary Predicate Device K082051** | **Comparison Same/Different** |
| **Device name** | NeuroOne OneRF™ Generator | Cosman RF Generator | N/A |
| **RF Output Frequency** | 465.1 kHz | 480 kHz | **Different** |
| **Maximum output power (Hardware)** | 50 watts | 50 watts | **Same** |
| **Maximum output power (Software)** | 2 watts | 50 watts | **Different** |
| **Power delivery modes** | Continuous and pulsed | Continuous and pulsed | **Same** |
| **AC Power Compatibility** | AC Line 100-240V | AC Line 100-240V | **Same** |
| **Lesion Creation** | Yes | Yes | **Same** |
| **Temperature Monitoring** | Yes | Yes | **Same** |
| **Temperature Range (ºC)** | 20 to 90 | 0 to 110 | **Different** |
| **Temperature Shut Off (ºC)** | 90 | >100 | **Different** |
| **Auto shutdown for temperature exceeding safe levels** | Yes | Yes | **Same** |
| **Electrical safety/EMC compliant** | IEC 60601-1 and IEC 60601-1-2 compliant | IEC 60601-1 and IEC 60601-1-2 compliant | **Same** |
| **RF energy delivery modes:** | • Manual control<br>• Temperature control | • Manual control<br>• Temperature control | **Same** |
| **RF energy delivery channel types** | Monopolar<br>Bipolar | Monopolar<br>Bipolar | **Same** |
| **User Touchscreen Interface** | Yes | Yes | **Same** |
| **USB Port updating software and downloading logs** | Yes | Yes | **Same** |

| **Technological and Performance Characteristics Comparison - RF Probe** | | | |
|---|---|---|---|
| | **Subject Device** | **Predicate Device K010202** | **Comparison Same/Different** |
| **Device name** | NeuroOne OneRF™ sEEG-RF Probe | Diros RF Probe (Tasker Intracranial Lesion Electrode) | N/A |
| **RF Probe Configuration** | Single open lumen probe (closed at tip) | Single closed lumen probe | **Same** |
| **Temperature Measurement Capabilities** | Yes | Yes | **Same** |
| **Location of Temperature Sensor** | On Temperature Accessory (inserted into lumen of probe) | Embedded in probe tip | **Different** |
| **Patient- Contact Materials** | Polyimide - electrode<br>Platinum - contact | Stainless steel<br>Insulation – (medical grade, abrasion resistant) | **Different** |
| **Compatibility with RF Generator** | Yes, NeuroOne RF Generator (using adapters) | Yes, Diros and Cosman RF Generators (using legally marketed adapters) | **Same** |
| **Key Dimensions:** | | | |
| **Electrode Active Length** | 2 mm | 2 mm | **Same** |
| **Diameter** | 0.8 mm | 0.8 mm | **Same** |
| **Number of Contacts** | 4 – 15 on each probe enabled for Ablation | 1 on each probe | **Different** |
| **Creation of Lesions in Nervous Tissue** | Yes | Yes | **Same** |
| **Comparative Lesion Size Testing in Ex-vivo Tissue** | Yes | Yes | **Same** |

| **System Characteristics** | |
|---|---|
| **System Characteristic** | **Identification** |
| **User** | Neurosurgeons familiar with RF lesion techniques |
| **Anatomical Site of Use** | Nervous tissue |
| **Access Method** | Intracranial |
| **EnergyType** | Radiofrequency |
| **Procedure Type** | Ablation |
| **Principle of Operation** | Operator controlled; RF delivered from RF generator to compatible sEEG - RF probes to create lesions in nervous tissue |
| **Mechanism ofAction** | 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 NeuroOne OneRF™ Ablation System. Performance testing of the subject device (system) was conducted to demonstrate that the device (system) 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 (width and length) of the lesion for each active electrode contact: temperature, time, configuration (monopolar, bipolar), mode (temperature control, manual). | Lesion sizes were determined based on time and temperature. Lesion size is comparable to predicate. |
| **Dimensional Verification and RFCB Cable Durability** | This testing was performed to evaluate the dimensional characteristics and to demonstrate compatibility between components. In addition, the flexural durability of the RFCB cables was tested. | Pass – The test results indicate that the sEEG-RF Probe / Temperature Accessory / Stylet / Spacer Tube and Radio Frequency Connector Box designs meet the dimensional and cable durability requirements. |
| **Mechanical Performance** | This testing was performed to verify specifications related to the mechanical interaction between the sEEG-RF Probe and Accessories | Pass – The test results indicate that the sEEG-RF Probe / Temperature Accessory / Stylet / Spacer Tube and Radio Frequency Connector Box designs meet the mechanical performance requirements |
| **Mechanical Integrity** | This testing was performed to evaluate the mechanical durability of the sEEG-RF Probe Accessories. | Pass - The test results indicate that the sEEG-RF Probe Accessories (Temperature Accessory and Radio Frequency Connector Box) designs meet the mechanical integrity requirements |
| **Ablation System Performance** | The purpose of this testing is to evaluate specifications related to energy delivery and temperature accuracy of the OneRF Ablation System including durability after use. | Pass - The test results indicate that the sEEG-RF Probe / Temperature Accessory / Stylet / Spacer Tube and Radio Frequency Connector Box designs meet the system performance requirements. |
| **Generator System** | This testing was performed to verify specifications related to the Generator and UI Software. | Pass – The test results indicate that the Generator and UI Software designs meet the system performance requirements. |
| **Electrical Safety** | Product shall meet the applicable requirements of Electromagnetic Compatibility and Electrical Safety standards - IEC 60601-1, -2, -6 and IEC 60601-2-2 | Pass – Met applicable requirements |
| **Temperature Accessory Kit and RFCB 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 F1980-16, ASTM 2096, ASTM F88without loss of function, sterility, or legibility. | Pass - The test results indicate that the sEEG-RF Probe Accessories (Temperature Accessory / Stylet / Spacer Tube and Radio Frequency Connector Box) 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 sterilization cycle was validated. |
| **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™ Ablation System has been found to be safe and effective for the intended users, uses, and use environments. |
| **Software** | Software was presented in accordance with FDA Guidance "*Content of Premarket Submissions for Software Contained in Medical Devices* "issued on: May 11, 2005). In addition, IEC 62304 was followed, as applicable | Software analysis addressed applicable requirements |
| **Cybersecurity** | Cybersecurity analysis was performed on the OneRF™ Ablation System in accordance with *"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"* – Final Guidance October 2, 2014 and *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Draft Guidance for Industry and Food and Drug Administration Staff"* – Draft Guidance April 7, 2022. | Cybersecurity analysis addressed applicable requirements |

| **Biocompatibility** | |
|---|---|
| **Biocompatibility Overview** | **Conclusions** |
| **Components tested**: sEEG Electrode (sEEG-RF Probe), Anchor Bolt, Cap with prolonged (>24 hours to 30 days) contact with tissue/bone. **Components tested:** Strain Relief, Lock Band, Stylet Assembly, Electrode Tail, and Electrode Connector with limited (<24 hours) contact with intact skin. | Passed – Reference (K211367/K222404) |
| 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 predicate devices have the same Intended Use, Device Regulation Number/Name/Identification and Product Codes. The differences in the Indications for Use and Fundamental Scientific Technology between the subject device, OneRF™ Ablation System (RF Generator and RF Probe) and the predicate RF Generator (Cosman) and RF Probe (Diros) 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). The OneRF™ Ablation System is substantially equivalent to the predicate devices.