November 16, 2023

NeuWave Medical, Inc.
Mohamed Shariff
Director of Regulatory Affairs
3529 Anderson Street
Madison, Wisconsin 53704

Re: K231738
Trade/Device Name: NEUWAVE™ Microwave Ablation System and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: November 17, 2023
Received: October 13, 2023

Dear Mohamed Shariff:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.11.16 15:59:44 -05'00'

Mark Trumbore, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231738

Device Name
NEUWAVE™ Microwave Ablation System and Accessories

Indications for Use *(Describe)*
The NEUWAVE™ Microwave Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue **in** percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors.

The NEUWAVE Microwave Ablation System is not indicated for use **in** cardiac procedures.

Type of Use *(Select one or both, as applicable)*
lZI Prescription Use (Part 21 CFR 801 Subpart D) 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 being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date: November 15, 2023

Company: NeuWave Medical Inc.
3529 Anderson Street
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FDA Establishment# 3008769756

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Device Information

Proprietary Name:	NEUWAVE™ Microwave Ablation System and Accessories
Common Name:	System, Ablation, Microwave and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Device Class:	Class II
Product Code:	NEY
CFR Section:	21 CFR 878.4400

Predicate Device

The NEUWAVE Microwave Ablation System and Accessories is substantially equivalent to the following currently marketed device:

Predicate Device - NEUWAVE Microwave Ablation System and Accessories [K220472 with predicate probe PRS15 (originally cleared as part of K200081) & NWSR25 (originally cleared as part of K130399)]

Indications for Use

The NEUWAVE™ Microwave Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors.

The NEUWAVE Microwave Ablation System is not indicated for use in cardiac procedures.

Device Description

The NEUWAVE Microwave Ablation System is a self-contained stand-alone system of hardware and software designed for the ablation of soft tissue, including the partial or complete ablation of non-resectable liver tumors, via applying microwave energy to produce tissue heating effects generating tissue necrosis.

The system consists of three major components:

(1) The system cart which contains the components necessary to deliver microwave power to the microwave ablation probes, monitor and control system functions, a graphical user interface for the user to interact with the system and a CO_2 based cooling system.
(2) Power Distribution Module (PDM), which allows power to be transferred from the system generator to the ablation probes.
(3) Range of microwave ablation probe accessories for energy delivery.

The system cart has a single 2.45 GHz signal microwave source with three 140W microwave power amplifiers, a touch-screen graphical user interface, and a CO_2 based cooling system for limiting the temperature of the ablation probe, handle, and cable.

The CO_2 cooling system enables the Tissu-Loc™ function, which involves formation of an ice ball to adhere the probe in place prior to starting ablation therapy. This helps eliminate probe migration during imaging (CT scans, ultrasounds, etc.) and additional probe placement. The cooling system is responsible for controlling the pressure of the incoming CO_2 gas from two E-sized CO_2 cylinders located on the back of the cart.

The graphical user interface allows the user to set, adjust and activate the power setting per probe, time setting for each probe, ability to synchronize ablation initiation on probes, ablation activation, cauterization activation, audible volume, probe temperature, and Tissu-Loc™ function.

Up to three (3) NEUWAVE Ablation Probes can connect to the PDM at once and the PDM allows power to be transferred from the system cart to the ablation probes.

The microwave ablation probes are accessories which transfer microwave energy from the system cart to the target tissue to create regions of thermal necrosis. Each probe contains thermocouples that monitor the temperature of the probe. The probes can be used for Surgical Mode or Ablation Mode with various limits of maximum selectable power based on the probe type.

The antenna of the NEUWAVE PR probe family is designed to limit the length of the ablation for instances when a shorter ablation zone is desired. NEUWAVE PR Probes were developed to provide physicians with an additional ablation probe option with a different ablation burn pattern compared with NEUWAVE LK/LN/SR probes. The NEUWAVE PR probes are designed to produce ablations that quickly encompass the tip of the probe while limiting the overall length of the ablation compared with other NEUWAVE ablation probes.

There are 2 changes covered by this 510(k) submission:

1. A new Microwave Ablation Probe, the Surgical PR Probe (PRS35), available for use with the NEUWAVE System.
2. Updates to the NEUWAVE System software to accommodate the new PRS35 probe and to implement various enhancements to the user experience and correct minor software anomalies that do not impact safety or effectiveness.

The new NEUWAVE Surgical PR Ablation Probe (PRS35) has a 11/13-gauge and 35cm length cannula with a 2.9m cable in length. The proposed PRS35 probe uses a similar cannula and antenna design to the predicate probes PRS15 & NWSR25, and the ablation pattern also closely resembles the above stated predicate. The longer cannula length is a primary purpose of the new probe to enable access to targets farther from the skin surface due to insufflation in laparoscopic procedures.

The subject embedded software utilizes the existing firmware and software architecture design, technological characteristics and functions but incorporates enhancements and features as described below:

- Procedure Profiles
- PRS35 Probe Support
- Planning: Time and Power Guide available without probe
- Cybersecurity
- Misc. Bug fixes
- Additional Languages to support country specific registration globally (Finnish, Norwegian, Turkish)

No changes were made to the currently marketed family of NEUWAVE Ablation Probes nor to any hardware aspects of the currently marketed NEUWAVE system cleared under K220472.

The selection of available ablation probes provides physicians with the opportunity to select the length, stiffness, burn pattern and number of probes to use to create a wide variety of ablation zone sizes and shapes.

Comparison of Subject Device and Predicate Device

The following table compares the subject device to the predicate device with respect to indications for use, and technological characteristics, forming the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Device Characteristics	Predicate Device	Subject Device
	NEUWAVE Microwave Ablation System and Accessories K220472 with predicate probe PRS15&NWSR25	**NEUWAVE Microwave Ablation System and Accessories with Added 35cm Surgical PR Probe**
Intended Use	To thermally ablate soft tissue using microwave energy	Same
Indications for Use	The NEUWAVE™ Microwave Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors. The NEUWAVE Microwave Ablation System is not indicated for use in cardiac procedures.	Same
Principles of Operation	The NEUWAVE Ablation Probes are used in conjunction with the NEUWAVE Microwave Ablation System. Microwave energy is generated by the NEUWAVE Microwave Ablation system and delivered to the ablation probe. The probe converts the currents flowing on the coaxial cable conductors into radiated microwave energy in the tissue. The microwave energy is applied to the target tissue, heating the tissue to the point of necrosis.	Same
Software Version	V3.1.1	V3.2.0
Probe Applications	Percutaneous, open surgical and in conjunction with laparoscopic surgical settings.	Same
User Interface Modes	Surgical and Ablation Mode	Same
Power Delivery Initiation Method	User Interface, Footswitch (Footswitch available in Surgical Mode only) or FingerSwitch	Same

Device Characteristics	Predicate Device NEUWAVE Microwave Ablation System and Accessories K220472 with predicate probe PRS15&NWSR25	Subject Device NEUWAVE Microwave Ablation System and Accessories with Added 35cm Surgical PR Probe
Probe Dimensions	NEUWAVE LK Probe Diameter: 15 gauge, Length: 15cm and 20cm Diameter: 17 gauge, Length: 15cm and 20cm NEUWAVE LN Probe Diameter: 17 gauge, Length: 15cm and 20cm NEUWAVE SR 25 Probe (Predicate Probe 1) Diameter: 13 gauge, Length: 25cm NEUWAVE PR Probe Diameter: 15 gauge, Length: 15cm and 20cm Diameter: 17 gauge, Length: 15cm and 20cm NEUWAVE Surgical PRS15 Probe (Predicate Probe 2) Diameter: 15 gauge, Length: 15cm	The probe dimensions for the predicate device(s) remains unchanged this 510k proposes to introduce: NeuWave Surgical PR Probe (PRS35) Diameter: 11/13 gauge, Length: 35cm
Generator Maximum Output Power	NEUWAVE LK Probe; NEUWAVE LN Probe; NEUWAVE SR Probe Ablation Mode and Surgical Mode: Single Probe is 140W, Two Probes is 95W, Three Probes is 65W NEUWAVE PR Probe Ablation Mode: Single Probe is 65W, Two Probes is 65W, Three Probes is 65W Surgical Mode: Single Probe is 95W, Two Probes is 95W, Three Probes is 65W NEUWAVE Surgical PR Probe Ablation Mode: Single Probe is 80W, Two Probes is 80W, Three Probes is 80W Surgical Mode: Single Probe is 110W, Two Probes is 110W, Three Probes is 80W	The generator maximum output power for the predicate device(s) remains unchanged. The proposed new probe maximum power output is provided and falls within the already available range. Ablation Mode: Single Probe is 140W, Two Probes is 110W, Three Probes is 80W Surgical Mode: Single Probe is 140W, Two Probes is 110W, Three Probes is 80W
Antenna Design	NEUWAVE LK Probe; NEUWAVE LN Probe; NEUWAVE SR Probe Triaxial Antenna NEUWAVE PR Probe Modified Triaxial Antenna NEUWAVE Surgical PR Probe Modified Triaxial Antenna	Same as PR Probe (Modified Triaxial Antenna)
Target Ablation Time	Up to 10 minutes as limited by software. User may ablate for additional time after 10 minutes of ablation completion.	Same
Planar Coagulation Time	5 seconds – 1 minute	Same

Device Characteristics	Predicate Device	Subject Device
	NEUWAVE Microwave Ablation System and Accessories K220472 with predicate probe PRS15&NWSR25	**NEUWAVE Microwave Ablation System and Accessories with Added 35cm Surgical PR Probe**
Accessories	Dual Probe Clip CT Table Mounting Adapter for PDM Surgical Table Mounting Adapter for PDM Foot switch (Locking USB or Standard USB)	Same

The subject and the predicate device are similar in terms of technological characteristics as microwave devices used to ablate soft tissue, including the partial or complete ablation of non-resectable liver tumors.

Sterilization

NeuWave Microwave Ablation Probes are provided to customers sterile. The probes are packed in thermoform plastic trays containing a single probe and sealed with a Tyvek lid prior to sterilization. The product is over-packed in an e-flute box to further protect the sterile barrier.

The validated sterilization method for NeuWave Microwave Ablation Probes is Ethylene Oxide. Device specific methods were developed using the "overkill" approach and validated per ISO 11135:2014. Results demonstrated a Sterility Assurance Level (SAL) of 10^{-6}. There are no changes made to the sterilization method or process for this 510k.

Shelf Life

Accelerated aging tests were conducted to confirm the validity of the 48-month shelf life for ablation probes.

Biocompatibility

The NEUWAVE Ablation Probes are classified as an External Communicating Device, Tissue/bone/dentin patient contact, with a contact duration of (<24) hours. Based on this categorization, per Table A.1 of Annex A of ISO 10993-1, Cytotoxicity, Sensitization, Irritation, Systemic Toxicity and Material Mediated Pyrogenicity tests were performed. The results of all testing demonstrated that the Ablation Probes are biocompatible.

Performance Data

Nonclinical Testing

Design Verification testing has been completed to assure that the modified NEUWAVE Microwave Ablation System and accessories with the NEUWAVE Surgical PR probe meets its design and performance specifications; this testing included:

- Probe Physical Attribute Testing

- Probe Ablation Performance Testing in ex-vivo liver, kidney, muscle and lung tissue
- Probe tissue adhesion testing
- Probe biocompatibility testing per ISO 10993 Series and FDA Guidance
- IEC 60601-1:" Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance"
- IEC 60601-1: "Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance"
- IEC 60601-1-6: "Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability"
- IEC 60601-2-6: "Medical Electrical Equipment Part 2-6: Particular Requirements For The Basic Safety & Essential Performance Of Microwave Therapy Equipment"
- IEC 60601-2-18: "Medical Electrical Equipment – Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment"

All testing passed, and all acceptance criteria were met.

Software Verification and Validation
Software verification and validation testing was conducted, and documentation is provided within the submission as recommended by "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* dated May 11, 2005.

Animal Data
No animal data was needed to support substantial equivalence.

Clinical Data
No clinical data was generated in support of this Premarket 510(k) Notification.

Conclusion
The subject device (PRS35) has the same intended use and is similar in technological characteristics to the predicate. The essential performance of the subject device system and accessories remain the same, with no change to safety or effectiveness. Based on the intended use, technological characteristics, and non-clinical performance data, the modified software of the NEUWAVE System with the newly designed PRS35 probe is substantially equivalent to the predicate device.