August 11, 2022

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

Re: K220472
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: July 6, 2022
Received: July 7, 2022

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 (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,

Colin Kejing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K220472

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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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:	August 8, 2022
Submitter Name/Address:	NeuWave Medical, Inc. Part of the Ethicon Family of Companies 3529 Anderson Street Madison, WI 53704
Contact Person:	Mohamed Shariff Associate Director, Regulatory Affairs Tel: (856) 449 9609 Fax: (608) 512 1508 Email: msharif3@its.jnj.com
FDA Establishment Registration #	3008769756

Device Identification

Trade/Proprietary Name:	NEUWAVE™ Microwave Ablation System
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Product Code:	NEY
CFR Section:	21 CFR 878.4400
Device Class:	Class II
Classification Panel:	General and Plastic Surgery Devices

Predicate Device

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

NEUWAVE™ Microwave Ablation System and Accessories cleared under K200081 on November 13, 2020.

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 which applies microwave energy to produce tissue heating effects generating tissue necrosis.

The system consists of three major components (1) a 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) a Power Distribution Module (PDM), and (3) a range of microwave ablation probe accessories for energy delivery.

The system 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 system.

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 generator 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 and time based on the probe type.

NEUWAVE™ LK, and NEUWAVE™ PR ablation probes are available in either 17- gauge or 15- gauge cannulas and are available in 15 cm and 20 cm lengths. These probes have a cable length of 1.4m.

NEUWAVE™ LN ablation probes are available only in 17-gauge cannulas and are available in 15 cm and 20 cm lengths. These probes have a cable length of 1.4m.

The model NEUWAVE™ SR ablation probes have a 13-gauge cannula and are available in a 25 cm length only. NEUWAVE™ SR probes have a cable length of 1.4m.

NEUWAVE™ Surgical PR Ablation Probes have a 15-gauge cannula and a 15 cm length. These probes have a 2.9m cable length and the probe tip has a non-stick coating that facilitates repeat ablations/Planar Coagulation and helps prevent ablated tissue from adhering to the tip of the probe.

The antenna of the NEUWAVE™ PR probe 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.

The wide selection of 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.

A surgical clip is a single use sterile surgical accessory designed to hold two microwave ablation probes together in a parallel configuration at a fixed distance apart to facilitate planar coagulation of soft tissue during a surgical resection.

An optional footswitch accessory can be connected to the system to control power delivery in Surgical Mode.

Ablation Confirmation software (previously cleared under K192427) is available as an optional feature for the NEUWAVE™ Microwave Ablation System. When this option is supplied, a second monitor is provided with the cart which hosts the Ablation Confirmation graphical user interface.

Comparison of Intended Use and Indications for Use

The subject device and predicate device have the same Intended Use and Indications for Use as shown in the table below.

Device Characteristics	**Predicate Device** **NEUWAVE™ Microwave Ablation System and Accessories (K200081)**	**Subject Device** **NEUWAVE™ Microwave Ablation System and Accessories with updated Hardware and Software**
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

Comparison of Technological Characteristics with Predicate Device

The subject and the predicate devices are similar in terms of technological characteristics as microwave devices used to ablate soft tissue.

The subject device NEUWAVE™ Microwave Ablation System includes some updated but functionally equivalent hardware components which were implemented due to component obsolescence, and a corresponding software update to support the updated hardware. No changes were made that impact the delivery of microwave energy and no changes were made to NEUWAVE™ Ablation probes or accessories.

Feature/Specification	**Predicate Device**	**Subject Device**
	NEUWAVE™ Microwave Ablation System and Accessories (K200081)	**NEUWAVE™ Microwave Ablation System and Accessories with updated Hardware and Software**
Software Version	V3.1.0 software	V3.1.1
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 Finger-Switch	Same

Feature/Specification	Predicate Device		Subject Device
	NEUWAVE™ Microwave Ablation System and Accessories (K200081)		**NEUWAVE™ Microwave Ablation System and Accessories with updated Hardware and Software**
Probe dimensions			
NEUWAVE™ LK Probe	Diameter: 15 gauge, Length: 15 cm and 20 cm Diameter: 17 gauge, Length: 15 cm and 20 cm		Same
NEUWAVE™ LN Probe	Diameter: 17 gauge, Length: 15 cm and 20 cm		Same
NEUWAVE™ SR Probe	Diameter: 13 gauge, Length: 25 cm		Same
NEUWAVE™ PR Probe	Diameter: 15 gauge, Length: 15 cm and 20 cm Diameter: 17 gauge, Length: 15 cm and 20 cm		Same
NEUWAVE™ Surgical PR Probe	Diameter: 15 gauge, Length: 15 cm		Same
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	Same
NEUWAVE™ PR Probe	Ablation Mode:	Single Probe is 65W, Two Probes is 65W, Three Probes is 65W	Same
	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	Same
	Surgical Mode:	Single Probe is 120W, Two Probes is 120W, Three Probes is 80W	
Antenna Design	Triaxial Antenna for NEUWAVE™ LK Probe, NEUWAVE™ LN Probe and NEUWAVE™ SR Probe		Same
	Modified Triaxial Antenna for NEUWAVE™ PR Probe and NEUWAVE™ Surgical PR Probe		Same

Feature/Specification	Predicate Device	Subject Device
	NEUWAVE™ Microwave Ablation System and Accessories (K200081)	**NEUWAVE™ Microwave Ablation System and Accessories with updated Hardware and Software**
Settable Parameters		
Power	NEUWAVE™ LK Probe, NEUWAVE™ LN Probe and NEUWAVE™ SR Probe: 20W-140W in 5W	Same
	NEUWAVE™ PR Probe: 20W-95W in 5 W increments (Ablation Mode maximum is 65W)	Same
	NEUWAVE™ Surgical PR Probes: 20W-120W in 5 W increments (Ablation Mode maximum is 80W)	Same
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
Accessories	Dual Probe Clip CT Table Mounting Adapter for PDM Surgical Table Mounting Adapter for PDM Foot switch (Locking USB or Standard USB)	Same

Performance Data

Nonclinical Testing

Design Verification testing has been completed to assure that the modified NEUWAVE™ Microwave Ablation System and accessories meets its design and performance specifications; this testing is summarized in the following table. Electrical safety testing, electromagnetic compatibility testing and ex-vivo ablation tissue testing was conducted in accordance FDA guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices. The subject device passed the system level test performance criteria with providing evidence of substantial equivalence between the subject and predicate device.

Test Performed	Description	Pass/Fail
Electrical Safety Testing	Electrical Safety testing was undertaken per IEC 60601-1 3rd Edition to demonstrate that the NEUWAVE™ Microwave Ablation System with NEUWAVE™ Probes is electrically safe	Pass
Electromagnetic compatibility (EMC) testing	Electromagnetic compatibility (EMC) testing was undertaken per IEC 60601-1-2 4th Edition to demonstrate that the NEUWAVE™ Microwave Ablation System with NEUWAVE™ Probes complies with the requirements for immunity, radiated and conducted emissions	Pass
Ex-vivo tissue ablation testing	Ex-vivo tissue testing was conducted to demonstrate ablation zone dimensions of the subject and predicate devices are substantially equivalent for identical power settings.	Pass

Software verification testing was conducted, and results passed as recommended by *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005.

Clinical Data

No clinical data was generated or is required to support of this Premarket 510(k) Notification.

Cybersecurity

Updates to the underlying operating system were performed to strengthen the cybersecurity posture of the system. Also, an assessment was performed to assure conformance to the FDA's "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" guidance document.

Sterilization

No sterilization data was generated or required to support of this Premarket 510(k) Notification.

Biocompatibility

No biocompatibility data was generated or required to support of this Premarket 510(k) Notification.

Standards

- 60601-1:2005+C1;A2, Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance
- 60601-1:2014 Ed.3, Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance
- 60601-1-6:2010 Ed.3+A1, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- 60601-2-6:2012 Ed.2, Medical Electrical Equipment Part 2-6: Particular Requirements For The Basic Safety & Essential Performance Of Microwave Therapy Equipment
- 60601-2-18:2009 Ed.3, Medical Electrical Equipment – Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment

Conclusion

There are no differences in fundamental technological characteristics of the subject and predicate devices, and the minor changes implemented do not impact the essential performance of the subject device system and accessories. Based on the intended use, technological characteristics, and validation/verification data, the modified NEUWAVE™ Microwave Ablation System and Accessories is substantially equivalent to the predicate.