November 13, 2020

NeuWave Medical, Inc.
Dan Kosednar
Regulatory Affairs Consultant
3529 Anderson Street
Madison, Wisconsin 53704

Re: K200081
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: October 13, 2020
Received: October 14, 2020

Dear Dan Kosednar:

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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200081

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:	11/12/2020
Company:	NeuWave Medical Inc. 3529 Anderson street Madison, WI 53704
FDA Establishment#	3008769756
Contact Person:	Dan Kosednar, Consultant dan.kosednar@neuwave.com Phone: 608-216-9902 Fax: 608-512-1509
Company Contact:	Neda Chini Senior Regulatory Affairs Program Lead Phone: 949-789-8656 Email: nchini@its.jnj.com

Device Name

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 878.4440

Predicate Device

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

- Predicate Device - Certus 140 2.45 GHz Ablation System and Accessories cleared under K173756 on October 24, 2018.
- Reference Device – CertuSurg^{GT} Surgical Tool cleared under K130399 on July 18th, 2013.

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.

There are 3 primary changes covered by this 510(k) submission:

1. A new Microwave Ablation Probe, the Surgical PR Probe (PRS15), available for use with the NEUWAVE System.

2. Updates to the NEUWAVE System software to accommodate the new PRS15 probe and to implement various enhancements to the user experience and correct minor software anomalies that do not impact safety or effectiveness.

3. Several minor design changes implemented since K173756 which were evaluated per FDA Guidance Deciding When To Submit a 510(k) for a Change to an Existing Device, October, 2017 and it was determined to NOT require a 510(k) prior to marketing, including an updated Dual Probe Clip which now accommodates both 17-gauge and 15-gauge ablation probes.

No changes were made to the existing family of NEUWAVE Ablation Probes nor to any hardware aspects of the existing NEUWAVE system.

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, 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), (3) a range of microwave ablation probe accessories for energy delivery.

The 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.

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.

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.

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.

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 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.

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.

A dual probe clip is a single use sterile surgical accessory designed to hold two microwave ablation probes (15 gauge or 17 gauge) together in a parallel configuration at a fixed distance apart to facilitate planar coagulation of soft tissue during a surgical resection using Surgical Mode.

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

Comparison of Intended Use and Indications for Use

The subject device differs from the predicate device by a minor modification to the Indications for Use to remove language deemed unnecessary as shown in the table below and the associated changes to the labeling.

Device Characteristics	**Predicate Device**	**Subject Device**
	NEUWAVE Microwave Ablation System and Accessories (K173756)	**NeuWave Microwave Ablation System and Accessories with Added NEUWAVE Surgical PR Probe**
Intended Use	To thermally ablate soft tissue using microwave energy	Same
Indications for Use	The NeuWave Medical Certus 140™ 2.45 GHz 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 Certus 140™ 2.45 GHz Ablation System is not indicated for use in cardiac procedures. The system is designed for facility use and should only be used under the orders of a clinician.	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.

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, including the partial or complete ablation of non-resectable liver tumors.

The subject device includes a new ablation probe, the NEUWAVE Surgical PR (PRS15) probe which uses the identical cannula, antenna design and ablation pattern as the predicate NEUWAVE PR (15cm, 15 gauge) probe (marketed as the PR15XT). The PRS15 probe has a longer (2.9 m) and more flexible cable than the predicate, but these components are identical to the cable used on the reference CertuSurg^{GT}. The longer, more flexible cable allows the user greater flexibility in the placement of the microwave ablation system cart relative to the patient bed and helps prevents cable management challenges. The PRS15 probe also has the identical non-stick material coating on the probe tip as the reference CertuSurg^{GT}. The non-stick coating facilitates repeat ablations/Planar Coagulation and helps prevent ablated tissue from adhering to the tip of the probe.

The maximum Ablation Mode power (80W) for use with PRS15 probe was selected to deliver equivalent power at the probe emitting point and result in equivalent ablation zone performance compared to the predicate PR15XT maximum power (65W in Ablation Mode). The higher limits for maximum power are required to compensate for the loss of microwave power in the longer cable length (i.e. microwave power dissipates as a function of length traveled). No changes were made to the maximum power settings for existing NEUWAVE ablation probes.

Minor software updates to the system were incorporated to modify the graphical user interface to include the PRS15 probe and implement enhancements for a visual ex-vivo ablation results guide on the touch screen. This guide provides ex-vivo ablation results when using probes at various power and time settings.

Feature/Specification	**Predicate Device** **NeuWave Microwave Ablation System and Accessories (K173756)**	**Subject Device** **NeuWave Microwave Ablation System and Accessories with Added PRS15**
Software Version	V3.0.X software	V3.1.X software
Probe Applications	Percutaneous, open surgical and in conjunction with laparoscopic surgical settings. The CertuSurg^{GT} surgical tool is for open surgical procedures only.	Same
User Interface Modes	Surgical and Ablation Mode	Same

Feature/Specification	Predicate Device NeuWave Microwave Ablation System and Accessories (K173756)	Subject Device NeuWave Microwave Ablation System and Accessories with Added PRS15
Power Delivery Initiation Method	User Interface or Footswitch (Footswitch available in Surgical Mode only)	Same
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	N/A	Diameter: 15 gauge, Length: 15 cm
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 Surgical Mode: Single Probe is 95W, Two Probes is 95W, Three Probes is 65W	Same
NEUWAVE Surgical PR Probe	N/A	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

Feature/Specification	Predicate Device NeuWave Microwave Ablation System and Accessories (K173756)	Subject Device NeuWave Microwave Ablation System and Accessories with Added PRS15
Antenna Design	Triaxial Antenna for NEUWAVE LK Probe, NEUWAVE LN Probe and NEUWAVE SR Probe	Same
	Modified Triaxial Antenna for NEUWAVE PR Probe	Same for NEUWAVE PR Probe and NEUWAVE Surgical PR Probe
Settable Parameters Power	NEUWAVE LK Probe, NEUWAVE LN Probe and NEUWAVE SR Probe: 20W-140W in 5W increments	Same
	NEUWAVE PR Probe: 20W-95W in 5 W increments (Ablation Mode maximum is 65W)	Same
	NEUWAVE Surgical PR Probes: N/A	NEUWAVE Surgical PR Probes: 20W-110W in 5 W increments (Ablation Mode maximum is 80W)
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)	Dual Probe Clip updated to accommodate both 17-gauge and 15-gauge probes. Other accessories remain unchanged.

Feature/Specification	Reference Device	Subject Device
	NeuWave Microwave CertuSurg^{GT} Ablation Tool (K130399)	**NeuWave Microwave Ablation System and Accessories with Added NEUWAVE Surgical PR Probe**
Probe Cable Length	2.9m	Same
Non-Stick Coating on Probe Tip	Non-Stick Coating applied to facilitate multiple ablations/planar coagulation to help prevent ablated tissue from adhering to probe tip	Same

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 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}.

The Dual Probe Clip (RCPK Probe Surgical Clip (DR-001193)) is sterilized via gamma radiation and was validated to have a minimum sterility assurance level of 10^{-6} Per ISO 11137-2 Method VDMax – Substantiation of 25kGy.

Shelf Life:

Accelerated aging tests were conducted to confirm the validity of the 48-month shelf life for ablation probes and 18 months for dual probe clips.

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.

Standards Testing

The NEUWAVE System and Accessories has been designed to comply with the applicable portions of various International Standards, including:

- IEC 60601-1:2012 (3.1 edition)
- IEC 60601-2-2: 2017

- IEC 60601-2-6:2012
- IEC 60601-1-2:2014
- EN ISO 11607-1:2009
- ISO 10993-1: 2009

The NEUWAVE System and Accessories and the predicate device are substantially equivalent in design concepts, technologies and materials. The NEUWAVE System and Accessories has been verified through testing that supports the compliance of the NEUWAVE System and Accessories to the standards listed above.

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
- Ablation Probe Characterization Testing in ex-vivo liver (bovine), lung (bovine) and kidney (porcine) tissue
- Comparative Ablation Performance Testing per FDA Guidance of subject PRS15 probe versus predicate PR15XT probe per in ex-vivo liver, kidney and muscle, including histological evaluations to support substantial equivalence
- Probe tissue adhesion testing
- Probe biocompatibility testing per ISO 10993 Series and FDA Guidance
- System Electrical Safety Testing per IEC 60601-1, Edition 3.1
- System EMC Testing per IEC 60601-1-2, 4th Edition
- System Testing to IEC 60601-2-2
- System Testing to IEC 60601-2-6

All testing passed, and all acceptance criteria were met.

Software verification and validation testing was conducted and documentation was 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

Given the lack of new risks associated with the subject device and the demonstrated equivalent ablation zone performance, all questions about the safety and substantial equivalence of the PRS15 to the predicate and references devices were sufficiently answered using ex-vivo and bench testing. In-vivo animal testing was not relied on in this premarket notification submission for a determination of substantial equivalence.

Clinical Data

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

Conclusion

There are minor differences in technological characteristics, but they do not impact the essential performance of the subject device system and accessories and they do not raise new questions of safety or effectiveness. Based on the intended use, technological characteristics, and non-clinical performance data, the modified NEUWAVE Microwave Ablation System and Accessories is substantially equivalent to the predicate device and reference device.