DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 9, 2017

NeuWave Medical, Inc.
Mr. Dan Kosednar
Director of Regulatory Affairs
3529 Anderson Street
Madison, Wisconsin 53704

Re: K163118
Trade/Device Name: NEUWAVE Flex 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: February 17, 2017
Received: February 21, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163118

Device Name
NEUWAVE Flex Microwave Ablation System and Accessories

Indications for Use *(Describe)*
The NEUWAVE™ Flex Microwave Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue.

The NEUWAVE™ Flex Microwave 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 physician.

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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Date:	03/06/2017
Subject:	510(k) Summary of Safety and Effectiveness Information for the NEUWAVE Flex Microwave Ablation System and Accessories

Company:	NeuWave Medical, Inc. 3529 Anderson Street Madison, WI 53704
FDA Establishment#	3008769756
Contact:	Dan Kosednar, Director of Regulatory Affairs P – 608-512-1592 F – 608-512-1509

Proprietary:	NEUWAVE Flex Microwave Ablation System and Accessories
Common:	System, Ablation, Microwave and Accessories
Classification:	Surgical Devices, 73 NEY, 21 CFR 878.4440

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

Predicate Devices

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

- Certus 140 2.45 GHz Ablation System and Accessories – Class II – 21CFG878.4400 which has been the subject of a cleared 510(k) with the FDA log number K100744, K113237, K122217, K130399 and K160936.

Indications For Use

The NEUWAVE™ Flex Microwave Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue.

The NEUWAVE™ Flex Microwave 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 physician.

Device Description

The design of the NEUWAVE Flex Microwave Ablation System (FLEX) is an evolution of the design of the legally marketed Certus 140 2.45GHz Ablation System (K160936). The FLEX is a fully featured soft tissue ablation system that uses small diameter flexible ablation probes, a single microwave source operating at 2.45 GHz, a CO2-based cooling system, a Power Distribution Module (PDM), and a support arm designed to hold the PDM in a user-selected position. Microwave energy is applied to the target tissue via a single flexible ablation probe, heating the tissue to the point of necrosis.

The FLEX is designed to be used in Target Ablation. Target ablation involves placing a probe into a substantial target and then ablating for up to several minutes until the target tissue is necrotic. The FLEX

is designed for ablations in soft tissue in percutaneous (via an introducer) procedures, open surgical procedures, and procedures in which the target tissue is accessed via a lumen or scope such as an endoscope or laparoscopic port.

Two microwave ablation probes are available for use with the NEUWAVE Flex Microwave Ablation System: the FLEX4 and the FLEX6. They are comprised of a conical tip on the end of a flexible cable and a connector assembly. The probe with the sharper tip (FLEX6) is designed for easier tissue penetration while the probe with the less sharp (FLEX4) tip designed for improved navigation. Both FLEX probe models are French gauge 6 (outer diameter of less than 2 mm) and 150 cm long. Both probe models have the same antenna design and ablation performance characteristics.

Each probe contains three (3) temperature measurement sensors that help monitor performance and ensure patient and operator safety.

The FLEX probe antenna was designed to produce an ablation zone substantially equivalent to the predicate Certus^{PR} probe but within a flexible probe shaft. Like the predicate Certus^{PR} probe, the FLEX probes are designed to produce ablations that encompass the tip of the probe while limiting the overall length of the ablation. Testing in ex-vivo liver, lung and kidney tissue confirm that the FLEX probes produce ablations that are substantially equivalent to the predicate probes.

A PDM and Accessories Support Arm (The Arm) holds the PDM in a user-selected position. The Arm attaches to an imaging/procedure table via a rail mount. This allows the PDM and probe to move with the patient, greatly reducing the potential for patient injury due to accidental probe movement.

The Arm is comprised of three jointed lengths with two tension knobs that allow the user to maneuver and fix the Arm at the user-selected position. The PDM mount on the ARM has a dovetail design with magnetic retention for quick and easy mounting. Additionally, the Arm has a grasping mechanism that can be used to hold a scope such as an endoscope (if used) in a fixed position for an extended period of time.

A CO_2 based cooling system ensures the non-active portion of the probe does not exceed temperature requirements.

The system uses two (2) customer supplied E-sized CO2 cylinders. The system monitors the pressure of the tanks and heats the tanks to maintain the desired tank pressure. The FLEX System will select which cylinder to initially use based upon tank pressures.

Comparison to Predicate

The FLEX Microwave Ablation System is an evolution of the predicate Certus 140 2.45GHz Ablation System and Accessories. Below is a tabular comparison of the similarities and differences:

Feature/Specification	**NEUWAVE Flex Microwave Ablation System**	**Predicate Certus 140 Ablation System and Accessories (K160936)**	**Comments/impact on safety and effectiveness**
Indication for Use	The NEUWAVE Flex Microwave Ablation System and Accessories is indicated for the ablation (coagulation) of soft tissue. The NEUWAVE Flex is not indicated for use in cardiac procedures.	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. The Certus 140 is not indicated for use in cardiac procedures.	The FLEX indications for use are a subset of the predicate indications.
Energy Source	2.45 GHz Frequency Modulated Source Microwave	2.45 GHz Frequency Modulated Source Microwave	No change from predicate
Power Distribution Module (PDM)	PDM mounts to the PDM and Accessories Support Arm and allows for the connection of a single (1) FLEX ablation probe.	PDM mounts to the imaging table rail and allows for the connection of up to three (3) ablation probes	The PDM concept and construct is similar to the predicate. However, the FLEX system only supports the use of a single ablation probe at a time.
Probe applications	The FLEX ablation probes can be used in multiple applications, including percutaneous (via an introducer), open surgical and procedures in which the target tissue is accessed via a lumen or scope such as an endoscope or coaxial introducer.	Percutaneous, open surgical and in conjunction with laparoscopic.	The nature of the flexible probe enables the FLEX system to be used in additional applications in which the target tissue is accessed via a lumen or scope such as an endoscope or coaxial introducer.
Probe dimensions	French 6 diameter and 150cm in length.	Certus^{LK}, Certus^{LN} and Certus^{PR} probes are 17 gauge and available in 15 and 20cm lengths. Certus^{SR} probe is 13 gauge and available only in a 25cm length. CertuSurg^{GT} has a 17 gauge cannula and is only available in one length (6cm).	The FLEX system uses a flexible ablation probe instead of the metal cannula-based percutaneous probes of the predicate.

Feature/Specification	**NEUWAVE Flex Microwave Ablation System**	**Predicate Certus 140 Ablation System and Accessories (K160936)**	**Comments/impact on safety and effectiveness**
Generator Output Power	The FLEX system allows an output of 40W – 100W. The user controls the power setting on the user interface and can adjust in 5 Watts increments.	Certus^{LK}, Certus^{LN} and Certus^{SR} Probes are limited to 140W for a single probe, 95W if 2 probes are selected and 65W if 3 probes are selected. Certus^{PR} Probes Maximum of 65W per probe regardless of the number of probes when used in Ablation Mode. In Surgical Mode, the maximum power for Certus^{PR} probes is 95W if one or two probes are used and 65W if three probes are used. For the CertuSurg^{GT}, the maximum power is 110W for a single probe, 95W if two probes are used and 65W if 3 probes are used.	The power levels available on the FLEX are a subset of the power levels on the predicate.
Antenna Design	Coaxial Antenna Flex probe	Triaxial Antenna for Certus^{LK}, Certus^{LN} and Certus ^{SR} Modified Triaxial Antenna for Certus^{PR} and CertuSurg^{GT}	The FLEX probe antenna was designed to produce an ablation zone substantially equivalent to the predicate Certus^{PR} probe but within a flexible probe shaft. Testing in ex-vivo liver, lung and kidney tissue confirm that the FLEX probes produce ablations that are substantially equivalent to the predicate probes.
Cooling Mechanism	CO_2 cooling using the Joule-Thompson effect of high pressure CO_2 gas	CO_2 cooling using the Joule-Thompson effect of high pressure CO_2 gas	The same CO_2 cooling method is employed to keep the non-active portions of the probe at acceptable temperatures.
Tissu-Loc Feature	No Tissu-Loc feature	Tissu-Loc feature	The predicate employs a Tissu-Loc feature to adhere the probe to tissue prior to delivering microwave energy. This feature is not available on the FLEX system.

Feature/Specification	**NEUWAVE Flex Microwave Ablation System**	**Predicate Certus 140 Ablation System and Accessories (K160936)**	**Comments/impact on safety and effectiveness**
Sterilization/Packaging			
Probe Sterilization Method	Ethylene Oxide	Ethylene Oxide	This aspect of system/probe design has not been modified from the predicate device.
Probe Packaging	Thermoformed plastic tray with Tyvek Lid, with E-flute outer box.	Thermoformed plastic tray with Tyvek Lid, with E-flute outer box.	The packaging used on the FLEX probes uses the same tray and lid as the predicate.
Monitored Parameters			
Elapsed Time Probe Temperature Coolant Level Power in Watts Coolant Pressure	Yes	Yes	This aspect of system/probe design has not been modified from the predicate device.
Alarms	The following parameters are monitored and will cause the FLEX system to stop delivering power if values are unacceptable:	The following parameters are monitored and will cause the Certus 140 to stop delivering power if values are unacceptable:	
	Gas Coolant Level Generator Temperature Probe Temperature Reflected Power Level Probe Communication Probe Authentication	Gas Coolant Level Generator Temperature Probe Temperature Reflected Power Level Probe Communication Probe Authentication	This aspect of system/probe design has not been modified from the predicate device.

Performance Data

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

- IEC 60601-1:2005 + CORR 1:2006, CORR 2:2007 + Amendment 1:2012
- IEC 60601-2-2:2009
- IEC 60601-2-6:2012
- IEC 60601-1-2:2007/AC:2010
- EN ISO 11607-1:2009
- ISO 10993-1: 2009

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

The system passed all pre-determined acceptance criteria identified in the test plan. Ex-vivo testing in bovine liver and lung and porcine kidney was conducted to produce data for the Instructions for Use and to compare to the predicate devices. Ex-vivo ablation sizes for the FLEX system were deemed to be substantially equivalent to the predicate devices.

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "Guidance on Software Contained in Medical Devices". Potential risks were analyzed and satisfactorily mitigated in the device design.