



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

May 4, 2016

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

Re: K160936

Trade/Device Name: Certus 140 2.45GHz Ablation System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories  
Regulatory Class: Class II  
Product Code: NEY  
Dated: April 1, 2016  
Received: April 4, 2016

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 yours,

**Jennifer R. Stevenson -A**

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

## Indications for Use

510(k) Number (if known)

K160936

Device Name

Certus 140 2.45GHz Ablation System and Accessories

Indications for Use (Describe)

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™ 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.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

Date: 05/04/2016  
Subject: 510(k) Summary of Safety and Effectiveness Information for the NeuWave Medical Certus 140 2.45 GHz Ablation System and Accessories

Company: NeuWave Medical, Inc.  
3529 Anderson Street  
Madison, WI 53704

FDA Establishment# 3008769756

Contact: Dan Kosednar, Director of Regulatory Affairs and Quality Assurance  
P – 608-512-1592  
F – 608-512-1509

Proprietary: Certus 140 2.45 GHz 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 Certus 140 2.45 GHz 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 and K130399.

#### **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.

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.

#### **Device Description**

The system has a single 2.45 GHz signal source generator and three (3) independent power amplifiers, each capable of producing up to 140W each. One, easy to use, touch-screen user interface controls the system. The User Interface can be set for either Ablation Mode or Surgical Mode. An optional footswitch can be connected to the system to control power delivery in Surgical Mode. Up to three (3) energy delivery accessories can be connected to and powered by the system at one time. An intermediate junction box or Power Distribution Module (PDM) reduces system set up complexity.

A variety of sterile, single-patient use energy delivery accessories (ablation probes and surgical tools) are available for use with the Certus 140. All are comprised of a sharp trocar on the end of a cannula, a handle, a cable and a connector assembly.

Models Certus<sup>LK</sup>, and Certus<sup>PR</sup> 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.

Models Certus<sup>LN</sup> 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 Certus<sup>SR</sup> ablation probe has a 13 gauge cannula and is available in a 25 cm length only. Certus<sup>SR</sup> probes have a cable length of 1.4m.

CertuSurg<sup>GT</sup> surgical tool is hand-held and has a 6cm, 17 gauge cannula designed specifically for surgical coagulation (including Planar Coagulation) in open surgical settings. This device has a finger-activated power delivery mechanism and a cable length of 2.9m.

#### Ablation Probe/Surgical Tool Design Application Overview

	Percutaneous Ablation	Laparoscopic Ablation	Open Surgical Ablation	Open Surgical Coagulation
Certus <sup>LK</sup>	X		X	X
Certus <sup>LN</sup>	X		X	
Certus <sup>PR</sup>	X		X	X
Certus <sup>SR</sup>		X	X	
CertuSurg <sup>GT</sup>			X*	X

\* The CertuSurgGT is not recommended for Target Ablation procedures lasting more than 1 minute.

Each energy delivery accessory contains temperature measurement sensors that help monitor performance and ensure patient and operator safety.

Additionally, the different percutaneous ablation probes have been designed to optimize the energy transfer efficiency from the probe into different types of tissue based on known electrical properties of each tissue.

Certus<sup>LK</sup> probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in liver and kidney tissue. Certus<sup>LN</sup> probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in lung tissue.

The antenna of the Certus<sup>PR</sup> probe is designed to limit the length of the ablation for instances when a shorter ablation zone is desired. Certus<sup>PR</sup> Probes were developed to provide physicians with an additional ablation probe designed specifically for ablating smaller lesions. The Certus<sup>PR</sup> probes are designed to produce ablations that quickly encompass the tip of the probe while limiting the overall length of the ablation. Certus<sup>PR</sup> probes will enable physicians to ablate smaller lesions while limiting necrosis of adjacent tissue when compared to other Certus probes.

The Certus<sup>SR</sup> probes length and gauge size result in a sturdy probe ideal for use in laparoscopic applications.

The CertuSurg<sup>GT</sup> surgical tool is designed to produce focal, rapid coagulation of soft tissue in open surgical applications, including planar coagulation performed prior to tissue resection.

A CO<sub>2</sub> based cooling system ensures the non-active portion of the probe does not exceed temperature requirements. Additionally, the CO<sub>2</sub> enables the Tissu-Loc function, which can be used to adhere or stick the probe in place prior to starting ablation therapy. This function is similar in use to the stick function available on cryogenic ablation systems. The CertuSurg<sup>GT</sup> surgical tool does not have the Tissu-Loc function.

The system uses two (2) E-sized CO<sub>2</sub> cylinders. When a tank in use empties, the system will automatically switch to using the other tank and notify the user to replace the empty tank.

An accessory, a small plastic probe clip that can hold two 17 gauge probes and allow the user to easily hold both while performing planar coagulation, is available.

Ablation Confirmation software (K150313) is available as an option on the Certus 140. When this option is supplied, a second monitor is provided with the system which hosts the Ablation Confirmation user interface.

### **Modifications**

This 510(k) was submitted to update the Certus 140 system with the following modifications:

- New 15 gauge probe variants for Certus<sup>PR</sup> and Certus<sup>LK</sup> probe types in 15cm and 20cm lengths.
- Minor updates to system cart including mechanical support for a second monitor display required for Ablation Confirmation (K150313)

### **Performance Data**

The Certus 140 2.45 GHz Ablation System and Accessories has been designed to comply with the applicable portions of various International Standards, including:

- IEC 60601-1:2005
- IEC 60601-2-2:2006
- IEC 60601-2-6:1984
- IEC 60601-1-2:2007
- EN ISO 11607-1:2009
- ISO 10993-1: 2009

The Certus 140 2.45 GHz Ablation System and Accessories and the predicate devices are substantially equivalent in design concepts, technologies and materials. The Certus 140 Ablation 2.45 GHz System and Accessories has been verified through rigorous testing that, in part, supports the compliance of Certus 140 2.45 GHz 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. Ablation sizes for 15 gauge probe variants 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.

Ex-vivo studies were conducted to compare the performance of the Certus 140 2.45 GHz Ablation System and Accessories to a predicate device.