



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

NeuWave Medical, Inc.
% Mr. Dan Kosednar
Director of Regulatory Affairs and Quality Assurance
3529 Anderson Street
MADISON WI 53704

May 9, 2017

Re: K171022
Trade/Device Name: Ablation Confirmation™
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 2, 2017
Received: May 3, 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A faint, large "FDA" watermark is visible in the background behind the signature.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K171022

Device Name
Ablation Confirmation™

Indications for Use (Describe)

Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the Certus® 140 2.45 GHz Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the Certus 140 user interface. AC imports images from CT scanners and facility PACS systems for display and processing during ablation procedures. AC assists physicians in identifying ablation targets, assessing proper ablation probe placement and confirming ablation zones. The software is not intended for diagnosis.

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
PRASStaff@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: 05/02/2017
Subject: 510(k) Summary of Safety and Effectiveness Information for NeuWave Medical's Ablation Confirmation™ image processing software

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: Ablation Confirmation™ Common: Computed Tomography X-ray System
Classification: Radiology, JAK, 21 CFR 892.1750

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

Predicate Devices

Ablation Confirmation™ is substantially equivalent to the following currently marketed device:

- Ablation Confirmation Software – Class II – 21CFR892.1750, Radiology, JAK, which has been the subject of a cleared 510(k) with the FDA log number K161285.

Indications For Use

Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the Certus® 140 2.45 GHz Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the Certus 140 user interface. AC imports images from CT scanners and facility PACS systems for display and processing during ablation procedures. AC assists physicians in identifying ablation targets, assessing proper ablation probe placement and confirming ablation zones. The software is not intended for diagnosis.

Device Description

AC is resident on the Certus® 140 system and is accessible to the physicians via a second, dedicated monitor with its own user interface separate from the ablation user interface. AC functions are controlled via a USB connected mouse. AC connects to a facility PACS system and CT scanner and receives and sends CT and MR images via the DICOM protocol.

AC contains a wide range of image processing tools, including:

- 2D image manipulation
- 3D image generation (from 2D images)
- 3D image manipulation
- Region of interest (ROI) identification, segmentation and measurement
- Automatic identification of ablation probes
- Registration of multiple images into a single view

Prior to an ablation procedure, physicians can use AC to semi-automatically segment and visualize ablation target lesions in soft tissue including liver, lung and kidney. The physician initiates the segmentation with tools provided on the screen. AC then uses segmentation algorithms to construct a 2-D visualization of the target lesion selected. The physician can accept the initial segmentation results or use AC tools to manually adjust the defined target lesion. Once accepted, the identified target is rendered into a 3D image.

Upon the placement of ablation probes, taking and importing the CT scan, AC can process the image and identify up to three ablation probes. AC can then perform a registration of the initial CT scan, containing the identified target with the second scan containing the ablation probe(s) in place. The resulting image allows the physician to visualize the ablation probe(s) in relation to the identified target. This enables physicians to ensure proper probe(s) placement prior to starting the ablation.

Following the ablation procedure and a post-procedure CT scan, AC allows the physician to semi-automatically segment and visualize the ablation zone using the same process as in the initial target segmentation. AC then performs a registration of the initial CT scan, containing the identified target, with the final CECT scan containing the segmented ablation zone. The physician also has the option to evaluate the effect of potential tissue contraction to help determine the technical success (ablation zone covers target lesion with desired amount of margin) of the ablation procedure.

All AC processing and viewing is accomplished at the Certus® 140 Ablation System without the physician having to leave the procedure area to utilize separate image processing tools.

Additionally, AC allows for the images to be viewed by a remote physician for time-saving clinical consultation on the current procedure.

Modifications

This 510(k) was submitted to update the Ablation Confirmation software with the following modifications:

- The available tissue contraction percentages vary by tissue type and have been expanded versus the predicate while remaining within the values supported by various peer-reviewed literature
- The user can configure the AC software so that tissue contraction is automatically applied when reaching the "Evaluate Ablation" page in the workflow rather than requiring a separate distinct action and additional processing time.

Performance Data

Ablation Confirmation™ was tested in accordance with a test plan that fully evaluated all functions performed by the software. The system passed all pre-determined acceptance criteria identified in the test plan.

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 arising from the expansion of the Tissue Contraction feature were analyzed and satisfactorily mitigated in the device design and labeling.

Substantial Equivalence Discussion

Ablation Confirmation™ is substantially equivalent in design concepts, technologies and materials to the identified predicate. AC does not present any new questions of safety or effectiveness.