October 3, 2019

NeuWave Medical, Inc.
% Neda Chini
Senior Regulatory Affairs Program Lead
3529 Anderson Street
MADISON, WI 53704

Re: K192427
Trade/Device Name: Ablation Confirmation
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 4, 2019
Received: September 5, 2019

Dear Neda Chini:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K192427

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 NEUWAVE Microwave Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the NEUWAVE Microwave Ablation System 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.

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K192427

Date:	08/28/2019
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:	Neda Chini, Senior Regulatory Affairs Program Lead P – 949-789-8656 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 K171022.

Indications For Use

Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the NEUWAVE Microwave Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the NEUWAVE Microwave Ablation System 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 NEUWAVE Microwave Ablation 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, fused PET 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 NEUWAVE Microwave 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:

- Improved automatic probe detection feature
- New feature for manual probe definition available for users when the software cannot automatically detect the ablation probes.
- Network communication monitoring – a new convenience feature to aid in troubleshooting network connectivity issues.
- Removed “Remote Viewing” feature based upon customer feedback
- Improvements to the target/ablation zone edit tools to allow the user to select if they want to edit a single slice or multiple slices
- An “undo/redo” capability for segmentation operations was added.
- Allow importation of a fused Positron Emission Tomography (PET) scan for use as a comparison scan. The fused images are created by another device and transmitted as a DICOM Secondary Capture image. Note that the fused PET/CT images are not able to be manipulated, processed or registered to another image using AC software. This feature addition simply allows fused PET/CT scans to be displayed as a “Comparison” scan within the existing AC construct. No measurements are allowed on the fused PET/CT scans.
- Allow the user to view the Set Up scan as a comparison scan when viewing the Evaluate Ablation screen.
- Render targets, ablations and ablation probes as semi-transparent (as opposed to opaque) to allow for better visualization of the objects relative to each other.

- Image registration improvements that include a “manual registration” process in place of the previous “Refine Registration” feature. Also, the addition of “undo” in the registration workflow as a user convenience feature.
- New function to measure the distance between probe tips when multiple probes are used.
- Displaying the diameter of the sphere when the user is placing/changing the size of a sphere to provide the user with additional information compared with previous software versions.

Feature/Specification	**Subject Device: Ablation Confirmation Software V3.1.0**	**Predicate: Ablation Confirmation Software V2.3.0 (K171022)**	**Same as predicate**	**Comments/impact on safety and effectiveness**
Indication for Use	Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the NEUWAVE MIcrowave Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the NEUWAVE Microwave Ablation System 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.	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.	Yes	No changes to the Indication For Use. The product name of the ablation system was updated to reflect a branding/name change.
Image Acquisition	The system is capable of retrieving CT image data, conforming to the DICOM standard. Additionally, fused PET images and MR images can be imported for the comparison scan feature.	The system is capable of retrieving CT image data, conforming to the DICOM standard. Additionally, MR images can be imported for the comparison scan feature.	No	The fused PET images are created by another device and transmitted as a DICOM Secondary Capture image. Note that the fused PET/CT images are not able to be manipulated,

Feature/Specification	**Subject Device: Ablation Confirmation Software V3.1.0**	**Predicate: Ablation Confirmation Software V2.3.0 (K171022)**	**Same as predicate**	**Comments/impact on safety and effectiveness**
				processed or registered to another image using AC software. This feature addition simply allows fused PET/CT scans to be displayed as a "Comparison" scan within the existing AC construct. No measurements are allowed on the fused PET/CT scans.
3D Image Manipulation	The system provides tools to manipulate the 3D image rendering. These tools include: • Rotation • Pan/Zoom • Window/Level • Distance between tips when multiple probes are detected	The system provides tools to manipulate the 3D image rendering. These tools include: • Rotation • Pan/Zoom • Window/Level	No	Addition of distance between probe tip measurement as a convenience feature for users. No new risks or required risk mitigations were identified and no impact on safety or effectiveness.
Region of Interest (ROI) Identification	The system allows the user to semi-automatically define regions of interest on CT images. A single-step "undo" function was added to this feature.	The system allows the user to semi-automatically define regions of interest on CT images.	No	"Undo" is a minor change and convenience feature for users . No new risks or required risk mitigations were identified and no impact to safety or effectiveness.
ROI Measurements	The system allows the user to assess the volume of the defined ROIs.	The system allows the user to assess the volume of the defined ROIs.	Yes	No changes in this submission
Desired Margin Identification	The system allows the users to draw on the ROI images to visualize a user-determined desired margin for the ablation procedure.	The system allows the users to draw on the ROI images to visualize a user-determined desired margin for the ablation procedure.	Yes	No changes in this submission
Registration	The system can perform deformable registration on two distinct CT images. The user can manually adjust the results of the registration process. Replaced 'Refine Registration' capability with a 'Manual Registration' capability. When using the manual registration, the user	The system can perform deformable registration on two distinct CT images. The user can manually adjust the results of the registration process.	No	Automatic registration algorithms and mechanisms remain unchanged. The manual registration option methodology has changed and an "undo" feature was added. No new risks were identified, no new risk mitigations were required

Feature/Specification	**Subject Device: Ablation Confirmation Software V3.1.0**	**Predicate: Ablation Confirmation Software V2.3.0 (K171022)**	**Same as predicate**	**Comments/impact on safety and effectiveness**
	has the option of turning off the deformations computed by the deformable registration.			and no impact to safety or effectiveness.
Probe Identification	The system can automatically identify ablation probes within the scan. AC can detect up to 3 probes. The software also enables the user to manually draw probes	The system can automatically identify ablation probes within the scan. AC can detect up to 3 probes.	No	Continuous improvement of existing probe detection feature. Ability to manual draw probes is a minor feature addition to improve feature set.
Probe placement Assessment	The system, using the deformable registration process, can visualize the position of the ablation probe(s) in relation to the ROI.	The system, using the deformable registration process, can visualize the position of the ablation probe(s) in relation to the ROI.	Yes	No changes in this submission
Ablation Zone Assessment	Using the same process as ROI identification, the system allows the user to semi-automatically identify the ablation zone following an ablation procedure.	Using the same process as ROI identification, the system allows the user to semi-automatically identify the ablation zone following an ablation procedure.	Yes	No changes in this submission
Allows User to Account for Tissue Contraction	Yes	Yes	Yes	No changes in this submission
Assessing the technical success of the ablation procedure.	Using the same deformable registration process, image set with ablation zone can be overlaid onto the image set with the initial ROI segmentation to help physicians determine the technical success of an ablation procedure. Allow user to view the Set Up scan next to the Evaluate Ablation scan.	Using the same deformable registration process, image set with ablation zone can be overlaid onto the image set with the initial ROI segmentation to help physicians determine the technical success of an ablation procedure	No	This change is a minor workflow enhancement based upon user feedback. No new risks or required risk mitigations were identified and no impact to safety or effectiveness.

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 new or updated features 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. This version of the AC software does not present any new questions of safety or effectiveness.