April 4, 2024

NeuWave Medical, Inc.
% Allison Francis
Regulatory Affairs Specialist
3529 Anderson Street
MADISON, WI 53704

Re: K232227
Trade/Device Name: ABLATE-IQ™
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 4, 2024
Received: March 4, 2024

Dear Allison Francis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232227

Device Name
ABLATE-IQ™

Indications for Use *(Describe)*
ABLATE-IQ™ assists physicians in identifying ablation targets, assessing proper ablation probe placement and visualizing treatment zones when used with the NEUWAVE Microwave Ablation System (NEUWAVE System). The software is not intended for diagnosis, to predict ablation volume, or to predict ablation success.

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: April 3, 2024

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

FDA Establishment# 3008769756

Submission Contact: Allison Francis
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Device Identification

Device Trade Name: ABLATE-IQ™
Common Name: System, X-Ray, Tomography, Computed
Classification Name: Computed tomography x-ray system
Device Class: Class II
Product Code: JAK
CFR Section: 21 CFR 892.1750

Predicate Device

ABLATE-IQ™ is substantially equivalent to the following currently marketed device:
Predicate Device – Ablation Confirmation (**K192427**)
NeuWave Medical, Inc.

Indications for Use

ABLATE-IQ™ assists physicians in identifying ablation targets, assessing proper ablation probe placement and visualizing treatment zones when used with the NEUWAVE Microwave Ablation System (NEUWAVE System). The software is not intended for diagnosis, to predict ablation volume, or to predict ablation success.

Device Description

ABLATE-IQ™ formally known as Ablation Confirmation, is a Computed Tomography (CT) image processing software package available as an optional feature for use with the NEUWAVE System. ABLATE-IQ™ 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. ABLATE-IQ™ functions are controlled via a USB connected mouse. ABLATE-IQ™ connects to a facility PACS system and CT scanner and receives and sends CT, fused PET and MR images via the DICOM protocol over the hospital network. DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into an electronic PACS.

ABLATE-IQ™ 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)/target identification, segmentation, and measurement
- Image-based detection of ablation probes manually placed by the user (physician)
- Registration of multiple images into a single view

Modifications

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

- Planning (New Premium Feature that is optionally licensed for 3.2.0): Probe Insertion Path Planning is an optional feature that allows the user to pre-plan the location and trajectory of the probe(s) relative to a pre-defined target(s). Proposed Ablation Zone Display allows the user to try different combinations of time and power derived from ex-vivo animal tissue data to help users visualize proposed ablation zones with targets and does not provide a clinical representation of tissue to be ablated.
- Reporting (New Premium Feature that is optionally licensed for 3.2.0): Generation of an electronic report containing procedural information (e.g., ablation time and power used), data related to the target, and the treatment zone dimensions is also a new optional software feature available. The resulting report can be stored to the Hospital PACS.
- Workflow Updates (page combinations): Prior to 3.2.0, the software had ten steps the user was required to step through. In 3.2.0, the ABLATE-IQ™ navigation groups similar workflow steps together under 3 major workflow pages.
- Profiles: The system can apply default settings for procedure selectable features and recall those in a procedure selectable way. The default settings do not control the NEUWAVE system nor probe output in any way.
- Cybersecurity: New cybersecurity features were added for additional protection and compliance

Comparison of Subject Device and Predicate Device

ABLATE-IQ™ software version 3.2.0 has the same or similar technological characteristics as the predicate device and therefore is substantially equivalent to the predicate device.

Attribute	Subject Device ABLATE-IQ™ K232227	Predicate Device Ablation Confirmation K192427	Comparison
Manufacturer	NeuWave Medical	NeuWave Medical	Same
Product Code	JAK	JAK	Same
Regulation Number	892.1750	892.1750	Same
Indications for Use	ABLATE-IQ™ assists physicians in identifying ablation targets, assessing proper ablation probe placement and visualizing treatment zones when used with the NEUWAVE Microwave Ablation System (NEUWAVE System). The software is not intended for diagnosis, to predict ablation volume, or to predict ablation success.	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.	Same, the subject device indications for use is the same as the underlined text from the predicate device. The verbiage of the Indications for Use of the subject device is slightly different than the declared predicate as the text is being reduced for clarity. The change in verbiage does not alter the intended use of the device as compared to the predicate device.

Attribute	Subject Device ABLATE-IQ™ K232227	Predicate Device Ablation Confirmation K192427	Comparison
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, fused PET images and MR images can be imported for the comparison scan feature.	Same
2D Image Manipulation	The system provides tools to manipulate the 2D image data. The tool set includes: • Window/Level • Pan/Zoom • Image Scrolling • Point measurement (HU and coordinate) • Distance measurement • Rotation	The system provides tools to manipulate the 2D image data. The tool set includes: • Window/Level • Pan/Zoom • Image Scrolling • Point measurement (HU and coordinate) • Distance measurement • Rotation	Same
3D Image Generation	The system is able to generate a 3D image based upon the 2D image series.	The system is able to generate a 3D image based upon the 2D image series.	Same
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 • Distance between tips when multiple probes are detected	Same

Attribute	Subject Device ABLATE-IQ™ K232227	Predicate Device Ablation Confirmation K192427	Comparison
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. A single- step "undo" function was added to this feature.	Same
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.	Same
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.	Same
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 has the option of turning off the deformations computed by the deformable 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 has the option of turning off the deformations computed by the deformable registration.	Same

Attribute	Subject Device ABLATE-IQ™ K232227	Predicate Device Ablation Confirmation K192427	Comparison
Probe Identification	The system can automatically identify ablation probes within the scan. ABLATE-IQ™ 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. The software also enables the user to manually draw probes.	Same
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.	Same
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.	Same
Allows User to Account for Tissue Contraction	Yes	Yes	Same
Tissue Contraction Ranges - Liver	ABLATE-IQ™ with V3.2.0 SW allows users to apply 0%, 10%, 15%, 20% or 30% tissue contraction to identified target during the "Evaluate Ablation Zone" step in the workflow or automatically based upon default settings.	Ablation Confirmation with V3.1.0 SW allows users to apply 0%, 10%, 15%, 20% or 30% tissue contraction to identified target during the "Evaluate Ablation Zone" step in the workflow or automatically based upon default settings.	Same

Attribute	Subject Device ABLATE-IQ™ K232227	Predicate Device Ablation Confirmation K192427	Comparison
Tissue Contraction Ranges - Kidney	ABLATE-IQ™ with V3.2.0 SW allows users to apply 0%, 10%, 15%, 20% or 30% tissue contraction to identified target during the "Evaluate Ablation Zone" step in the workflow or automatically based upon default settings.	Ablation Confirmation with V3.1.0 SW allows users to apply 0%, 10%, 15%, 20% or 30% tissue contraction to identified target during the "Evaluate Ablation Zone" step in the workflow or automatically based upon default settings.	Same
Tissue Contraction Ranges - Lung	ABLATE-IQ™ with V3.2.0 SW allows users to apply 0%, 10%, 20%, 30%, 40% or 50% tissue contraction to identified target during the "Evaluate Ablation Zone" step in the workflow or automatically based upon default settings	Ablation Confirmation with V3.1.0 SW allows users to apply 0%, 10%, 20%, 30%, 40% or 50% tissue contraction to identified target during the "Evaluate Ablation Zone" step in the workflow or automatically based upon default settings.	Same
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. Allow user to view the Set Up scan next to the Evaluate Ablation scan.	Same

Attribute	Subject Device ABLATE-IQ™ K232227	Predicate Device Ablation Confirmation K192427	Comparison
Snapshots	User can take snapshots of any view and send to the facility PACS for achieving, if desired.	User can take snapshots of any view and send to the facility PACS for achieving, if desired.	Same
Remote Viewing	No remote viewing capability	No remote viewing capability	Same
Orthogonal 2D Viewing	Axial, Sagittal, Coronal, "Needle" and "Periscope" presentation options.	Axial, Sagittal, Coronal, "Needle" and "Periscope" presentation options.	Same
Workflow	3 workflow pages Prior to 3.2.0, the software had ten steps the user was required to step through. In 3.2.0, the ABLATE-IQ™ navigation groups similar workflow steps together under 3 major workflow pages.	10 workflow pages	Different
Reporting	New optional reporting feature added for version 3.2.0 software.	No reporting feature available.	Different
Profiles	The system can apply default settings for procedure selectable features and recall those in a procedure selectable way. The default settings do not control the NEUWAVE system nor probe output in any way.	No profile feature available.	Different
Planning	New optional feature added for software version 3.2.0.	No planning feature available.	Different

Attribute	Subject Device ABLATE-IQ™ K232227	Predicate Device Ablation Confirmation K192427	Comparison
Cybersecurity	ABLATE-IQ™ V3.2.0 is a software only device resident on the NEUWAVE Microwave Ablation System. Cybersecurity updates were made to software V3.2.0 on the NEUWAVE Microwave Ablation System. Cybersecurity updates in V3.2.0 software on the NEUWAVE Microwave Ablation System include: • Whitelisting Amendments • Shell Lockdown Amendments • Firewall Rule Amendments • Bitlocker • Remove Remote Code • Component Removal Cleanup	Ablation Confirmation V3.1.0 is a software only device resident on the NEUWAVE Microwave Ablation System. Cybersecurity controls in V3.1.0 software on the NEUWAVE Microwave Ablation System include: • Whitelisting • Shell Lockdown • Firewall	Similar. The NEUWAVE Microwave Ablation System software V3.2.0 includes new cybersecurity features for additional protection and compliance.

Non-Clinical and/or Clinical Tests Summary & Conclusions

ABLATE-IQ™ was tested in accordance with an established test plan that fully evaluated all functions performed by the software. Design verification documents were developed to provide evidence for unit, integration, system level, regression, information security, and validation software tests. Additionally, User Requirement, Design Requirement, and Design Specification testing was reports were developed. The ABLATE-IQ™ software 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.

ABLATE-IQ™ software V3.2.0 is substantially equivalent in design concepts, technologies and operating principle to the identified predicate. This version of the ABLATE-IQ™ does not present any new questions of safety or effectiveness.

Conclusion

The subject device, ABLATE-IQ™ software version 3.2.0, has the same or similar technological characteristics as the predicate device and therefore is substantially equivalent to the predicate device. Based on the intended use, technological characteristics, and non-clinical performance data, the modified software of ABLATE-IQ™ is substantially equivalent to the predicate device.