R.A.W. Srl
℅ Chiara Ferrari
Q&R Officer
Via Soperga 13
Milan, 20127
ITALY

September 12, 2023

Re: K222938
Trade/Device Name: Ablation-fit
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QTZ
Dated: August 10, 2023
Received: August 10, 2023

Dear Chiara Ferrari:

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,

Jessica Lamb, PhD
Assistant Director
Imaging Software 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222938

Device Name
Ablation-fit

Indications for Use *(Describe)*
Ablation-fit is a medical imaging application available for use with liver ablation procedures.
Ablation-fit is used to assist physicians in planning, permitting the graphical display of anatomy involved in the procedure, ablation targets and ablation needle placement.
Ablation-fit is used to assist physicians in confirming ablation zones during follow-up.
The software is not intended for diagnosis. The software is not intended to predict ablation volumes or 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.

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

"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."

510(k) Summary

I. Submitter

Manufacturer: R.A.W. S.r.l.
Address: Via Soperga 13, 20127 Milan, Italy
Phone: +39 3400747597

Contact Person: Chiara Ferrari
Applicant Correspondent: Chiara Ferrari
Email: quality@endo-sight.it
Date Prepared: August 10th, 2023

II. Device

510(k) Number	K222938
Device Name	Ablation-fit
Trade or Proprietary Name:	Ablation-fit
Common or Usual Name:	Ablation-fit
Classification Name:	Medical image management and processing system
Primary Product Code:	QTZ
Regulation Number:	21 CFR 892.2050
Regulatory Class	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

Primary predicate device:

- Aline Ablation Intelligence - Class II – 21 CFR 892.2050, Radiology, LLZ, which has been the subject of a cleared 510(k) with the FDA log number K202297.

510(k) Number	K202297
Trade Name	Aline Ablation Intelligence
Manufacturer	Mirada Medical Ltd
Device Name	Aline Ablation Intelligence
Regulation Number	892.2050
Regulation Name	Picture archiving and communications system
Regulatory Class	II
Primary Product Code	LLZ

Reference device:
The following reference device, which shares similar planning functions with Ablation-fit, is used in this submission to support the claim regarding the level of concern associated with Ablation-fit.

- Visible Patient Suite- Class II – 21 CFR 892.2050, Radiology, LLZ, which has been the subject of a cleared 510(k) with the FDA log number K212896.

510(k) Number	K212896
Trade Name	Visible Patient Suite
Manufacturer	Visible Patient, SAS
Device Name	Visible Patient Suite
Regulation Number	892.2050
Regulation Name	Medical image management and processing system
Regulatory Class	II
Primary Product Code	LLZ

IV. Device Description

Ablation-fit is a stand-alone medical imaging software that integrates Reconstruction, Segmentation, Registration and Visualization algorithms into a user interface to support physicians during liver ablation treatments planning and follow-up.
Ablation-fit allows to perform the entire workflow from DICOM (Digital Imaging and COmmunications in Medicine) images to 3D reconstruction of volume of interests, ablation probe placement and treatment outcome verification.

Specifically, Ablation-fit main functionalities include:

- Image loading from different supports (including PACS),
- DICOM images handling and visualization in axial, sagittal, coronal views,
- image segmentation,
- tools for manual edit of segmentations,
- 3D visualization,
- virtualization of ablation probe placement,
- pre- and post-treatment images registration.

The software permits segmentation and 3D reconstruction of volumes of interest. The software contours all of this anatomic information not only in axial, sagittal, and coronal planes for 2D visualization, but also three-dimensionally. Every computed segmentation can be manually modified in the 2D axial visualization and consequently the three-dimensional mapping of the scan changes accordingly.
Ablation-fit let the user simulate the virtual needle insertion and shows the desired ellipsoid of ablation.
Once the ablation procedure has been performed, pre- and post-treatment scans are registered. Consequently, the software can verify whether the ablation zones entirely surrounds the lesion and the safety margin.

V. Indications for Use

Ablation-fit is a medical imaging application available for use with liver ablation procedures.
Ablation-fit is used to assist physicians in planning, permitting the graphical display of anatomy involved in the procedure, ablation targets and ablation needle placement.
Ablation-fit is used to assist physicians in confirming ablation zones during follow-up.
The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.

VI. Comparison of Technological Characteristics

Characteristic		Ablation-fit	Aline Ablation Intelligence	Equivalence
Manufacturer		R.A.W. s.r.l.	Mirada Medical Ltd	N/A
510(k) number		K222938	K202297	N/A
Classification		Class II. 892.2050 QTZ	Class II. 892.2050 LLZ	N/A
Clinical equivalence	Target Population	The intended patient population of the Ablation-fit software is the patient demographic chosen by physicians to undergo liver ablation treatment (including patient with soft tissue lesions).	The intended patient population of the Aline Ablation Intelligence software is the patient demographic chosen by physicians to undergo ablation treatment (including patient with soft tissue lesions).	Ablation-fit target population is limited to liver ablation treatment.
	Where used	The software is intended to be used: • In operating rooms • In office environments within hospitals	The application's use environment is the Operating Room and the hospital healthcare environment such as interventional radiology control room.	Equivalent
	Site in the body	Liver	Not specified	Ablation-fit is intended to be used only on liver
	Intended Users	Physicians	Physicians	Equivalent
Technical equivalence	Design	stand-alone desktop software application with tools and features designed to assist users in planning ablation procedures as well as tools for evaluating ablation procedure's outcome	stand-alone desktop software application with tools and features designed to assist users in planning ablation procedures as well as tools for evaluating ablation procedure's outcome	Equivalent
	Energy Used and/or Delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	Equivalent
	Supported modalities	Contrast-enhanced CT	CT, MR	Ablation-fit does not support MR modalities
	Data visualization	• 2D visualization tools: Window and level, pan, zoom, cross-hairs, slice navigation. • 3D visualization of all segmented abdomen structures	• 2D visualization tools: Window and level, pan, zoom, cross-hairs, slice navigation. • 3D visualization of segmented targets/ablation zones.	Ablation-fit can visualize 3D spatial rendering of all segmented structures. These additional anatomical segmentations have the goal to highlight the presence of the anatomy to the user when

				planning intervention
	Data segmentation	• Automatic segmentation for liver, spleen, bones, liver vessels, skin • Tools for interactive segmentation for liver, spleen and liver targets/ablation zone • Tools for manual segmentation editing and/or correction	• No automatic segmentation of organs • Tools for interactive segmentation of targets/ablation zone • Tools for manual segmentation editing and/or correction	Ablation-fit provides an automatic segmentation of abdomen organs
	Planning function	Overlaying and positioning virtual ablation needles and user-selected estimates of the ablation regions onto the medical images	Overlaying and positioning virtual ablation needles and user-selected estimates of the ablation regions onto the medical images	Equivalent
	Data registration	• Automatic image registration of pre- and post-treatment images • Blending tools to assess the correctness of the registration	• Automatic image registration of pre- and post-treatment images • Manual registration correction	Ablation-fit has not a manual registration correction, but it provides a tool for the assessment of the correctness of the registration
	Ablation confirmation function	Ablation-fit can perform registration of pre-treatment, containing the identified targets and post-treatment scans containing ablation zone. The segmented and registered volumes between the two scans (targets, ablation zones) are then showed together on the same scan and in 3D. In addition, different colors enhance the residual target volume and safety margins.	Aline Ablation Intelligence can perform a registration of the planning scan, containing the identified target tissue, with the confirmation scan showing the ablation zone. The delineated target tissue on the planning scan is then projected onto the confirmation scan and overlaid onto the delineated ablation zone segmentation. This to help the user in analyzing if the ablation zone covers the target tissue with the desired amount of margin.	Equivalent

Ablation-fit is substantially equivalent to its predicate device with respect to:

- Image acquisition of CT images
- Image segmentation of targets and ablation zones
- Segmentation interactive tools and possible manual corrections
- 3D visualization of targets and ablation zones
- Virtual ablation needles and user-selected estimates of the ablation regions onto the medical images
- Automatic image registration of pre- and post-treatment images

- Overlay of targets and ablation zones in 3D and 2D visualization

The main differences between Ablation-fit and its predicate device concern the following aspects:

- Ablation-fit is intended to be used only for liver ablation procedures
- Ablation-fit is not intended to be used with MR images. This is clearly stated on labeling and indication for use.
- Ablation-fit performs image segmentation of abdominal structures, enabling computation of 3D volumes and providing accurate 3D representations of segmented structures and their spatial relationships. This allows the highlighting of anatomical structures to the user when planning interventions. In the predicate device, only targets and ablation zones are 3D segmented. Nevertheless, all segmentation processes underwent extensive validation, demonstrating their compliance with acceptance criteria. Moreover, the reference device we have included in this submission (Visible Patient Suite - K212896) presents similar functions for organ segmentation (including liver, bones, vessels) and is used for planning purposes, as specified in its intended use.
- Ablation-fit does not provide manual registration correction. Instead, Ablation-fit permits to assess the correctness of the image registration providing the blending tool.

The subject software has the similar intended use and technological/functional features as its predicate device in providing tools and workflow designs to support physicians during liver ablation treatments planning and follow-up. The slight differences between the subject and predicate device (supported modalities, data visualization and data segmentation, data registration) do not raise new questions of safety and effectiveness as demonstrated by verification and validation activities. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of Ablation-fit to the identified predicate device.

VII. Performance Data

Ablation-fit was designed and developed according to the software life-cycle process described in ANSI AAMI IEC 62304:2006/A1:2016.
First, a design and development project plan was defined, together with software requirements. They were transformed into software design specifications and software architecture. Specific tests are then planned and performed to verify both software units and software integration of the requirements.
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.".

Bench tests that compare the output of all segmentation and registration processes with ground truth annotated by qualified experts show that the algorithms performed as expected. Additionally, all semi-automatic functionalities underwent testing by three radiologists to account for variability resulting from user interaction. Quantitative testing related to these topics has been performed according to "*Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions Guidance*".

Also, a user acceptance test was performed according to ANSI AAMI IEC 62366-1:2015+AMD1:2020. This user acceptance test performs both verification and validation of Ablation-fit.

Measurement Accuracy Test was also performed in order to evaluate the accuracy of measurements carried out with Ablation-fit software on CT images.

Additionally, to supplement the software validation for Ablation-fit, we conducted software testing using retrospective image data of ablation procedures. The purpose of such analysis was to retrospectively evaluate the accuracy of Ablation-fit in assessing the outcome of lesion percutaneous thermal ablations and the accuracy of the automatically performed segmentations.

Performance, functional, and algorithmic testing outcomes show that Ablation-fit satisfies the device's user demands and requirements, which are deemed to be substantially equivalent to those of the predicate device.

VIII. Conclusion

In conclusion, Ablation-fit functions at least as safely and effectively as the designated predicate device and is essentially equivalent to it, according to performance tests and device evaluations contained in this 510(k) submission. Ablation-fit meets requirements for safety and effectiveness and does not introduce any new potential safety risks.