TechsoMed Medical Tehnologies, Ltd.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street
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PHILADELPHIA PA 19103

August 28, 2023

Re: K223639
Trade/Device Name: VisAble.IO
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QTZ, LLZ and QIH
Dated: July 31, 2023
Received: August 1, 2023

Dear Janice Hogan:

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)*

K223639

Device Name

VisAble.IO

Indications for Use *(Describe)*

VisAble.IO is a Computed Tomography (CT) image processing software package available for use with liver ablation procedures.

VisAble.IO is controlled by the user via a user interface.

VisAble.IO imports images from CT scanners and facility PACS systems for display and processing during liver ablation planning.

VisAble.IO is used to assist physicians in planning liver ablation procedures, including identifying ablation targets and virtual ablation needle placement. VisAble.IO is used to assist physicians in confirming ablation zones.

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.

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510(k) SUMMARY

TechsoMed's VisAble.IO

K223639

Submitter

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Contact Person: Dalia Dickman, PhD.

Date Prepared: August 23rd, 2023

Name of Device: VisAble.IO

Common or Usual Name: VisAble.IO

Classification Name: Medical Image Management and Processing System (21 CFR 892.2050)

Regulatory Class: Class II

Product Code: QTZ, QIH, LLZ

Predicate Devices

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	Class II
Primary Product Code	LLZ

Device Description

VisAble.IO is a stand-alone software application with tools and features designed to assist users in planning ablation procedures as well as tools for treatment confirmation. The use environment for VisAble.IO is the Operating Room and the hospital healthcare environment such as interventional radiology control room.

VisAble.IO has five distinct workflow steps:

- Data Import
- Anatomic Structures Segmentation (Liver, Hepatic Vein, Portal Vein, Ablation Target)

- Instrument Placement (Needle Planning)
- Ablation Zone Segmentation
- Treatment Confirmation (Registration of Pre- and Post-Interventional Images; Quantitative Analysis)

Of these workflow steps, two (Anatomic Segmentation and Instrument Placement) make use of the planning image. These workflow steps contain features and tools designed to support the planning of ablation procedures. The other two (Ablation Zone Segmentation, and Treatment Confirmation) make use of the confirmation image volume. These workflow steps contain features and tools designed to support the evaluation of the ablation procedure's technical performance in the confirmation image volume.

Key features of the VisAble.IO Software include:

- Workflow steps availability
- Manual and automated tools for anatomic structures and ablation zone segmentation
- Overlaying and positioning virtual instruments (ablation needles) and user-selected estimates of the ablation regions onto the medical images
- Image fusion and registration
- Compute achieved margins and missed volumes to help the user assess the coverage of the ablation target by the ablation zone
- Data saving and secondary capture generation

The software components provide functions for performing operations related to image display, manipulation, analysis, and quantification, including features designed to facilitate segmentation of the ablation target and ablation zones.

The software system runs on a dedicated computer and is intended for display and processing, of a Computed Tomography (CT), including contrast enhanced images.

The system can be used on patient data for any patient demographic chosen to undergo the ablation treatment.

VisAble.IO uses several algorithms to perform operations to present information to the user in order for them to evaluate the planned and post ablation zones. These include:

- Segmentation
- Image Registration
- Measurement and Quantification

VisAble.IO is intended to be used for ablations with the following ablation instruments:

For needle planning, the software currently supports the following needle models:

- Medtronic: Emprint Antenna 15CM, 20CM, 30CM
- NeuWave Medical: PR Probe 15CM, 20CM; PR XT Probe 15CM, 20CM; LK Probe 15CM, 20CM; LK XT Probe 15CM, 20CM

For treatment confirmation (including segmentation and registration), the software is compatible with all ablation devices as these functions are independent from probes/power settings.

Intended Use / Indications for Use

VisAble.IO is a Computed Tomography (CT) image processing software package available for use with liver ablation procedures.

VisAble.IO is controlled by the user via a user interface.

VisAble.IO imports images from CT scanners and facility PACS systems for display and processing during liver ablation procedures.

VisAble.IO is used to assist physicians in planning liver ablation procedures, including identifying ablation targets and virtual ablation needle placement. VisAble.IO is used to assist physicians in confirming ablation zones.

The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.

Technological Characteristics Comparison

Both the subject and predicate device are stand-alone software applications with tools and features designed to assist users in planning liver ablation procedures as well as tools for treatment confirmation. The use environment for both the subject and predicate device is the Operating Room and the hospital healthcare environment such as interventional radiology control room. Both the subject and predicate device have the same five distinct workflow steps:

• Data Import

• Anatomic Structures Segmentation (Ablation Target Segmentation only for Aline Ablation Intelligence)

• Instrument Placement (Needle Planning)

• Ablation Zone Segmentation

• Treatment Confirmation (Registration of Pre- and Post-Interventional Images; Quantitative Analysis)

The following technological differences exist between the subject and predicate devices:

The primary difference between devices is that the subject device includes an additional software feature to the user that provides initial 3D segmentation of vessels and anatomy of the liver. In addition, while the predicate device supports image processing of both Computed Tomography (CT) as well as Magnetic Resonance (MR), the subject device supports image processing of CT only. A table comparing the key features of the subject and predicate devices is provided below.

Characteristic	**VisAble.IO**	**Aline Ablation Intelligence**
510(K) number	K223639	K202297
Classification	Class II. 892.2050 QTZ, QIH, LLZ	Class II. 892.2050 LLZ

Indications for Use	VisAble.IO is a Computed Tomography (CT) image processing software package available for use with liver ablation procedures. VisAble.IO is controlled by the user via a user interface. VisAble.IO imports images from CT scanners and facility PACS systems for display and processing during liver ablation procedures. VisAble.IO is used to assist physicians in planning liver ablation procedures, including identifying ablation targets and virtual ablation needle placement. VisAble.IO is used to assist physicians in confirming ablation zones. The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.	Aline Ablation Intelligence is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures. Aline Ablation Intelligence is controlled by the user via a user interface on a workstation. Aline Ablation intelligence imports images from CT and MR scanners and facility PACS systems for display and processing during ablation procedures. Aline Ablation Intelligence is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. Aline Ablation Intelligence is used to assist physicians in confirming ablation zones. The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.
Target Population	The intended patient population is the patient demographic chosen by interventional radiologists to undergo ablation treatment (including patient with soft tissue lesions).	The intended patient population is the patient demographic chosen by interventional radiologists to undergo ablation treatment (including patient with soft tissue lesions).
Where Used	The application's use environment is the Operating Room and the hospital healthcare environment such as interventional radiology control room.	The application's use environment is the Operating Room and the hospital healthcare environment such as interventional radiology control room.
Energy Used	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

Intended Users	Physicians	Physicians
Design: Supported modalities	CT	CT;MRI
Design: Data Visualization	Window and level, pan, zoom, cross-hairs, slice navigation	Window and level, pan, zoom, cross-hairs, slice navigation
Design; Image Segmentation	Tools for segmenting 3D VOIs, including target tissues, ablation zones, vessels and anatomy of the liver.	Tools for segmenting 3D VOIs, including target tissues and ablation zones.
Design: Image registration	Registration of multiple images into a single view.	Registration of multiple images and imaging modalities into a single view.
Design: Ablation zone confirmation	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 helps the user in analyzing if the ablation zone covers the target tissue with the desired amount of margin.	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 helps the user in analyzing if the ablation zone covers the target tissue with the desired amount of margin.
Design: Save key images	Key images can be acquired which may be saved locally.	Key images can be acquired which may be saved back to PACS or any DICOM nodes.

Performance Data

VisAble.IO is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission.

The results of performance, functional and algorithmic testing demonstrate that VisAble.IO meets the user needs and requirements of the device, which are considered to be substantially equivalent to those of the listed predicate device.

Performance testing (Bench) was performed on the following features, to ensure that performance and accuracy was as expected:

- Segmentation post-processing Testing
- Image Registration Testing
- Measurement and Quantification Testing

The liver segmentation and liver vessel segmentation algorithms are AI algorithms. The training and model validation dataset characteristics are as follows:

Liver Segmentation Algorithm:

- Patients
  - 1091 contrast-enhanced CT images from arterial or venous phases in axial orientation
  - Age distribution: 50.70 ± 24.14
  - Sex distribution: 34.58% female, 65.42% male
  - Location of clinical sites: Germany, France, Turkey, Japan, Israel, Netherlands, Canada, USA, UK
- Imaging procedure: Contrast-enhanced CT images taken for diagnostic reading
- Number of clinical sites: 38

Liver Vessel Segmentation Algorithm:

- Patients
  - N=393 contrast-enhanced CT images from the portal-venous or late venous phases in axial orientation
  - Age distribution: 51.40 ± 22.81
  - Sex distribution: 37.43% female, 62.57% male
  - Location of clinical sites: Central Europe, North America, East Asia
- Imaging procedure: Contrast-enhanced CT images taken for diagnostic reading in liver diagnosis
- Number of clinical sites: 36

The following table provides a summary of the validation results:

Algorithm	N	Gender	Mean Age	N per Region	CT Brand	Primary Performance Goal	Primary Endpoint
Liver Segmentation	50	M: 52% F: 48%	60.6	US: 32 OUS: 18	GE Medical Systems, Siemens	Mean DICE =0.92	Mean DICE =0.98
Ablation Target Segmentation	59	M: 54% F: 46%	60.0	US: 30 OUS: 29	GE Medical Systems, Siemens, Philips	Mean DICE = 0.70	Mean DICE = 0.80
Ablation Zone Segmentation	59	M:64% F: 36%	66.0	US: 30 OUS: 29	GE Medical Systems, Siemens	Mean DICE = 0.70	Mean DICE = 0.86
Liver Vessels Segmentation	100	M: 52% F: 48%	58.5	US: 72 OUS: 28	GE Medical Systems, Siemens	Mean DICE = 0.70	Mean DICE = 0.72
PrePost Ablation Image Registration	46	M: 59% F: 41%	63.3	US: 13 OUS: 33	GE Medical Systems, Siemens, Philips	MCD*= 6.06 mm	MCD*=4.11 mm

*MCD=Mean Corresponding Distance

VisAble.IO provides functions including linear distance measurements and volumetric measurements. The resolution of the medical image data directly affects the ability of the user to make definitive measurements, especially when the sizes of structures to identify, segment or measure are near the resolution of the image data. The software's functions are dependent on the user actions as well as on the available information in the provided medical image data.

Segmentation tools provided within VisAble.IO include manual and semiautomated segmentation, and system post-processing of segmentations to remove 2D-holes and/or disconnected 3D regions present. The use of the segmentation tools to achieve a satisfactory delineation of ablation target or ablation zone is a user operation and the clinical accuracy of segmentation is the responsibility of the user and not a VisAble.IO function.

Registration tools provided within VisAble.IO include automated local rigid registration within a region of interest around user-segmentations of ablation targets and ablation zones. Final accuracy of registration is dependent on user assessment and manual modification of the registration prior to acceptance, and not a VisAble.IO function.

Measurements of the achieved margins and missed volumes, calculated by comparing the segmentations, are presented by the system following user acceptance of segmentations and registration as clinically accurate. Accuracy of linear distance measures calculated by VisAble.IO are dependent on the image resolution.

Test planning was performed in accordance with standard testing procedures and guidelines as listed in internal development processes.

Verification and validation testing were carried out as per planned arrangements in the Project Test Plan and Phase Test Plan(s) to ensure that design outputs meet design inputs and that this edition of VisAble.IO meets the product acceptance criteria. These are 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" and adherence to the DICOM standard.

Potential risks were analyzed and satisfactorily mitigated in the device design.

Based on the use-related risk analysis, it was determined that all potential use errors identified would not result in serious harm to patients or operators. Risk controls were also added to mitigate the use-related risks as much as possible, and the potential harm remains low. Therefore, no critical tasks were identified and human factors validation testing is not required to evaluate the use-related risks.

Conclusions

The VisAble.IO is as safe and effective as the Aline Ablation Intelligence. The VisAble.IO has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the VisAble.IO and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the VisAble.IO is as safe and effective as the Aline Ablation Intelligence. Thus, the VisAble.IO is substantially equivalent to the predicate device.