September 8, 2025

Techsomed Medical Technologies
Dalia Dickman
Head of Regulatory Affairs
6 Ofra Haza St.
Or Yehuda, 6032303
Israel

Re: K251931
Trade/Device Name: BioTraceIO Vision (V1.7)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QTZ, QIH, LLZ
Dated: July 13, 2025
Received: July 14, 2025

Dear Dalia Dickman:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for

Jessica Lamb, Ph.D.
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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251931 |

Please provide the device trade name(s).

BioTraceIO Vision (V1.7)

Please provide your Indications for Use below.

BioTraceIO Vision is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures.
BioTraceIO Vision is controlled by the user via a user interface.
BioTraceIO Vision imports images from CT and MR scanners and facility PACS systems for display and processing during ablation procedures.
BioTraceIO Vision is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. BioTraceIO Vision 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K251931

**510(K) SUMMARY**

**Techsomed's BioTraceIO Vision**

**Submitter**

Techsomed Medical Technologies LTD.

6 Ofra Haza St.
Or Yehuda 6032303
ISRAEL
Phone: +972545595951

Contact Person: Dalia Dickman, PhD.

Date Prepared: September 4, 2025

**Name of Device:** BioTraceIO Vision (V1.7)

**Common or Usual Name:** BioTraceIO Vision

**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** | **K240773** |
|---|---|
| Trade Name | BioTraceIO Vision 1.4 |
| Manufacturer | Techsomed Medical Technologies. LTD. |
| Device Name | VisAble.IO |
| Regulation Number | 892.2050 |
| Regulation Name | Medical Image Management and Processing System |
| Regulatory Class | Class II |
| Primary Product Code | QTZ, QIH, LLZ |

**Device Description**

BioTraceIO Vision 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 BioTraceIO Vision is the Operating Room and the hospital healthcare environment such as interventional radiology control room.

BioTraceIO Vision has six distinct workflow steps:

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

- Instrument Placement (Needle Planning) for Microwave Ablation (MWA) or Cryoablation (Cryo) Procedures
- Ablation Zone/Ice ball Segmentation
- Registration of Pre-Procedure Images
- Treatment Confirmation (Registration of Pre- and Post-Interventional Images; Quantitative Analysis)

Of these workflow steps, four (Anatomic Segmentation, Ablation Target Segmentation, Registration of Pre-Procedure Images 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 BioTraceIO Vision Software include:

- Workflow steps availability
- Manual and automated tools for anatomic structures and ablation target/zone segmentation
- Overlaying and positioning virtual instruments (ablation needles) and user-selected estimates of the ablation regions onto the medical images
- Image 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) and Magnetic Resonance (MR), including contrast enhanced images.

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

BioTraceIO Vision 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

BioTraceIO Vision is intended to be used for ablations with the following ablation instruments:

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

- Microwave ablation
  - AngioDynamics: Solero Probe 14CM, 19CM, 29CM
  - HS HOSPITAL SERVICE: Amica Probe (16G) 15CM, 20CM, 27CM; Amica Probe (14G) 15CM, 20CM, 27CM
  - Medtronic Covidien: Emprint Antenna 15CM, 20CM, 30CM
  - NeuWave Medical: LK Probe 15CM, 20CM; LK XT Probe 15CM, 20CM; PR Probe 15CM, 20CM; PR XT Probe 15CM, 20CM
  - Varian Medical Systems: Ximitry Probe 15CM, 20CM, 27CM

- Cryo ablation
  - Boston Scientific: IceForce 2.1 CX, CX L; IcePearl 2.1 CX, CX L; IceRod 1.5 CX; IceSeed 1.5 CX, CX S;Ice Sphere 1.5 CX
  - IceCure Medical: ProSense 10G Spheric, Elliptic 14CM, Elliptic 18.5CM; ProSense 13G Spheric, Elliptic
  - Varian Medical Systems: ISOLIS 2.1 E Probe 15CM, 20CM; ISOLIS 2.1 S Probe 15CM, 20CM; RA Slimline 1.7 15CM, 20CM; RA Slimline 1.7 Round 15CM, 7CM; RA Slimline 2.4 15CM, 23CM; RA 3.8 13CM, 28CM; V-Probe

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**

BioTraceIO Vision is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures.

BioTraceIO Vision is controlled by the user via a user interface.

BioTraceIO Vision imports images from CT and MR scanners and facility PACS systems for display and processing during ablation procedures.

BioTraceIO Vision is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. BioTraceIO Vision 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.

**Summary of Technological Characteristics**

Both the subject and predicate device are 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 both the subject and predicate device is the Operating Room and the hospital healthcare environment such as interventional radiology control room.

The software components of the subject and predicate device 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.

Both the subject and predicate device have the same six distinct workflow steps:

- Data Import
- Anatomic Structures Segmentation (Liver, Kidney, Hepatic Vein, Portal Vein, Ablation Target)
- Instrument Placement (Needle Planning) for Microwave Ablation (MWA) or Cryoablation (Cryo) Procedures
- Ablation Zone Segmentation
- Registration of Pre-Procedure Images
- Treatment Confirmation (Registration of Pre- and Post-Interventional Images; Quantitative Analysis)

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

The primary difference is the addition of support for kidney ablation procedures (MWA and cryoablation) using Computed Tomography (CT), whereas the predicate device was limited to liver ablation procedures using CT and Magnetic Resonance (MR). The modifications include kidney-specific segmentation algorithms and CT registration algorithms, as well as user interface updates to support ablation modality selection and cryoablation-specific visualizations. The UI enhancements introduced for cryoablation are applicable to both kidney and liver cryoablation procedures. These differences do not raise new questions of safety or effectiveness, as performance data demonstrate that BioTraceIO Vision is as safe and effective as the predicate device.

A table comparing the key features of the subject and predicate devices is provided below.

**SUBSTANTIAL EQUIVALENCE COMPARISON TABLE**

| | **Subject Device**<br>**BioTraceIO Vision (Ver 1.7)** | **Predicate Device**<br>**VisAble.IO (Ver 1.4)**<br>***Renamed as BioTraceIO Vision*** | **Comments** |
|---|---|---|---|
| **510(k) number** | TBD | K240773 | |
| **Classification** | Class II 892.2050 QTZ, QIH, LLZ | Class II 892.2050 QTZ, QIH, LLZ | Same |
| **Intended Use** | The intended patient population is patients chosen by interventional radiologists to undergo ablation treatment (including patients with soft tissue lesions). | The intended patient population is patients chosen by interventional radiologists to undergo ablation treatment (including patients with soft tissue lesions). | Same |
| **Indications for Use** | BioTraceIO Vision is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures.<br><br>BioTraceIO Vision is controlled by the user via a user interface.<br><br>BioTraceIO Vision imports images from CT and MR scanners and facility PACS systems for display and | BioTraceIO Vision (is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with liver ablation procedures.<br><br>BioTraceIO Vision is controlled by the user via a user interface.<br><br>BioTraceIO Vision imports images from CT and MR scanners and facility PACS systems for display and | The term “liver” was removed from the Indications for Use to reflect expanded support for kidney ablation procedures. Core functionality remains unchanged; BioTraceIO Vision continues to provide image import, visualization, segmentation, registration, and planning tools for |

| | | | |
|---|---|---|---|
| | processing during ablation procedures.<br><br>BioTraceIO Vision is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. BioTraceIO VIsion is used to assist physicians in confirming ablation zones.<br><br>The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success. | processing during liver ablation procedures.<br><br>BioTraceIO Vision is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. BioTraceIO Vision is used to assist physicians in confirming ablation zones.<br><br>The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success. | ablation procedures. Existing liver registration algorithms were adapted for kidney anatomy and segmentation algorithms were developed for kidney anatomy. These modifications represent an extension of established functionality and do not raise new questions of safety or effectiveness. Performance testing of V1.7 supports equivalence to the predicate device. |
| **User Population** | Qualified trained physicians | Qualified trained physicians | Same |
| **Where used** | The application's use environment is the Operation Room and the hospital healthcare environment such as interventional radiology control room | The application's use environment is the Operation Room and the hospital healthcare environment such as interventional radiology control room | Same |
| **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 | Same |
| **Technological Characteristics** | BioTraceIO Vision 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 the device is the Operating Room and the hospital healthcare environment such as | BioTraceIO VIsion is a stand-alone software application with tools and features designed to assist users in planning liver ablation procedures as well as tools for treatment confirmation. The use environment the device is the Operating Room and the hospital healthcare environment such as | Same |

| | | | |
|---|---|---|---|
| | interventional radiology control room. BioTraceIO Vision has six distinct workflow steps:<br>• Data Import<br>• Anatomic Structures Segmentation<br>• Instrument Placement (Needle Planning)<br>• Ablation Zone Segmentation<br>• Registration of Pre-Procedure Images<br>• Treatment Confirmation (Registration of Pre- and Post-Interventional Images; Quantitative Analysis) | interventional radiology control room. BioTraceIO Vision has six distinct workflow steps:<br>• Data Import<br>• Anatomic Structures Segmentation<br>• Instrument Placement (Needle Planning)<br>• Ablation Zone Segmentation<br>• Registration of Pre-Procedure Images<br>• Treatment Confirmation (Registration of Pre- and Post-Interventional Images; Quantitative Analysis) | |
| **Design: Supported modalities** | CT, MR | CT, MR | Same |
| **Design: Data Visualization** | Window and level, pan, zoom, cross- hairs, slice navigation | Window and level, pan, zoom, cross- hairs, slice navigation | Same |
| **Design; Image Segmentation** | Tools for segmenting 3D VOIs, including target tissues, ice ball (for cryoablation), ablation zones, vessels, liver and kidney. | Tools for segmenting 3D VOIs, including target tissues, ablation zones, vessels and liver. | Addition of tools for segmenting 3D VIOs for kidney. These modifications represent an extension of established functionality and do not raise new questions of safety or effectiveness. Performance testing of V1.7 supports equivalence to the predicate device. |

| | | | |
|---|---|---|---|
| **Design: Image registration** | Registration of multiple images and imaging modalities into a single view. | Registration of multiple images and imaging modalities into a single view. | Same |
| **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 analysing 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 analysing if the ablation zone covers the target tissue with the desired amount of margin. | Same |

**Performance Data**

BioTraceIO Vision 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 BioTraceIO Vision 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 Testing
- Image Registration Testing
- Measurement and Quantification Testing

The liver segmentation, liver vessel segmentation and kidney segmentation algorithms for CT and MR (MR for liver only) processing are AI algorithms. The training dataset characteristics are as follows:

Liver Segmentation Algorithm for CT Processing:

- 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 Segmentation for MR Processing:

- Patients
  - 418 MR images from arterial and venous phase
  - Age distribution: 64.30 ± 13.99
  - Sex distribution: 26.86% female, 73.14% male
  - Location of clinical sites: Central Europe
  - Imaging procedure: MR images taken for diagnostic reading
  - Number of clinical sites: 3

Liver Vessel Segmentation Algorithm for CT processing:

- Patients
  - 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

Kidney Segmentation for CT processing:

- Patients:
  - 300 contrast-enhanced preoperative CT images in axial orientation
  - Age distribution: 58.9 ± 13.8
  - Sex distribution: 40.0% female, 59.7% male, 0.3% other
  - Location of clinical sites: North America
  - Imaging procedure: Contrast-enhanced CT images taken for diagnostic reading and planning of nephrectomy surgery
  - Number of clinical sites: 2

The following table provides a summary of the validation results:

| Imaging Modality | Algorithm | | Metric | Performance |
|---|---|---|---|---|
| **Organ Segmentation** | | | | |
| CT | Liver Segmentation | | Mean DICE | 0.98 |
| MR | Liver Segmentation | | Mean DICE | 0.93 |
| CT | Kidney Segmentation**** | | Mean DICE | 0.91 |
| **Ablation Target Segmentation** | | | | |
| CT | Liver Ablation Target Segmentation | | Mean DICE | 0.82 |
| CT | Kidney Ablation Target Segmentation | 1 stroke*** | Mean DICE | 0.79 |
| | | 2 strokes*** | Mean DICE | 0.79 |
| | | 3 strokes*** | Mean DICE | 0.79 |
| MR | Liver Ablation Target Segmentation | | Mean DICE | 0.76 |
| **Ablation Zone Segmentation** | | | | |
| CT | Liver Ablation Zone Segmentation | | Mean DICE | 0.88 |
| CT | Kidney Ablation Zone Segmentation | 1 stroke*** | Mean DICE | 0.76 |
| | | 2 strokes*** | Mean DICE | 0.77 |
| | | 3 strokes*** | Mean DICE | 0.78 |
| CT | Kidney Ice Ball Segmentation | 1 stroke*** | Mean DICE | 0.80 |
| | | 2 strokes*** | Mean DICE | 0.81 |
| | | 3 strokes*** | Mean DICE | 0.83 |
| **Vessel Segmentation** | | | | |
| CT | Liver Vessels Segmentation* (HV+PV) | | Mean DICE | 0.72 |
| | | | Mean Centerline DICE | 0.76 |
| **Registration** | | | | |
| CT/MR | Liver Registration Pre-ablation MR – Pre-ablation CT | | MCD** | 5.04 mm |
| CT | Kidney Registration Diagnostic CT – Pre-ablation CT | | MCD** | 4.61 mm |
| CT | Liver Registration Pre-ablation CT – Post-ablation CT | | MCD** | 4.09 mm |
| CT | Kidney Registration Pre-ablation CT – Post-ablation CT | | MCD** | 3.06 mm |
| CT/MR | Liver Registration Pre-ablation MR – Post-ablation CT | | MCD** | 4.75 mm |

*Liver vessel segmentations range from a minimum of 2nd order branches to a maximum of 6th order branches; **MCD = Mean corresponding distance; ***Stroke – user input based on defined procedure to draw the strokes as defined in labeling;**** The kidney segmentation function of the device has been validated on CT images acquired from GE and Siemens scanners only and in patients with fewer than five (5) renal tumors.

BioTraceIO Vision 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 BioTraceIO Vision include manual and semi-automated segmentation. 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 BioTraceIO Vision function.

Registration tools provided within BioTraceIO Vision 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 BioTraceIO Vision 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 BioTraceIO Vision 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 BioTraceIO Vision 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.

**Conclusions**

The BioTraceIO Vision (1.7) is as safe and effective as the cleared BioTraceIO Vision (K240773). The BioTraceIO Vision 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 BioTraceIO Vision and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the BioTraceIO Vision (1.7) is as safe and effective as the cleared BioTraceIO Vision (K240773). Thus, the BioTraceIO Vision is substantially equivalent to the predicate device.