December 27, 2024

TechsoMed Medical Technologies Ltd.
Dalia Dickman
Head of Regulatory Affairs
Meir Weisgal 2
REHOVOT, 7654055
ISRAEL

Re: K243084
Trade/Device Name: BioTraceIO Precision (2.0)
Regulation Number: 21 CFR 892.2052
Regulation Name: Post-Ablation Tissue Response Prediction Software
Regulatory Class: Class II
Product Code: QZL
Dated: December 2, 2024
Received: December 2, 2024

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,

Shahram Vaezy -S for

Digitally signed by Shahram Vaezy -S
Date: 2024.12.27 13:58:03 -05'00'

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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)*
K243084

Device Name
BioTraceIO Precision (2.0)

Indications for Use *(Describe)*

BioTraceIO Precision is intended to provide physicians with adjunctive information in their clinical assessment of ablation zone created by liver tissue ablation, as part of their overall post-procedure clinical assessment.
BioTraceIO Precision generates and depicts a map (BioTrace Map or BTM) post-procedure, that correlates with image findings seen with Contrast-enhanced Computed Tomography (CECT) obtained at 24hours post treatment. The information is provided in the 2D ultrasound plane. This is the only plane and location displayed. No imaging of other portions of the ablation zone is available.

During the ablation procedure BioTraceIO Precision overlays the reference ablation zone (RAZ) provided by the ablation device manufacturer on the ultrasound image.
BioTraceIO Precision is indicated for use in patients undergoing radiofrequency (RF) or microwave (MW) liver ablation procedures.

BioTraceIO Precision is not intended for standalone prediction or for diagnostic purposes. BioTraceIO Precision does not support the use of multiple needles, either simultaneously or consecutively.
Manual ablation target contours and margins as defined by the user are not intended for diagnosis, to predict ablation volumes or predict ablation success.
The physician should not rely on BioTraceIO Precision BTM alone in decisions about patient management post treatment nor should BioTraceIO Precision serve as a substitute for any other assessment method, e.g., CT scans.

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

K243084

TechsoMed's BioTraceIO Precision

Submitter

TechsoMed Medical Technologies. LTD.

Meir Weisgal 2 Rehovot Israel

Phone: +972545595951

Contact Person: Dalia Dickman, PhD.

Date Prepared: September 26, 2024

Name of Device: BioTraceIO Precision (2.0)

Common or Usual Name: BioTraceIO Precision

Classification Name: Post-Ablation Tissue Response Prediction Software (CFR 892.2052)

Regulatory Class: Class II

Product Code: QZL

Predicate Device

510(k) Number	**DEN230020**
Trade Name	BioTraceIO Precision
Manufacturer	TechsoMed Medical Technologies. LTD.
Device Name	BioTraceIO Lite
Regulation Number	892.2052
Regulation Name	Post-Ablation Tissue Response Prediction Software
Regulatory Class	Class II
Primary Product Code	QZL

Reference Device

510(k) Number	**K240773**
Trade Name	BioTraceIO Vision
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
Product Code	QTZ, QIH, LLZ

Device Description

BioTraceIO Precision is a stand-alone software application with tools and features designed to assist users in their clinical assessment of ablation zone created by liver tissue ablation, as part of their overall post-procedure clinical assessment.

BioTraceIO Precision is a software application that uses a proprietary computational algorithm to analyze ultrasound images captured during liver ablation treatment (microwave ablation [MWA] or radiofrequency ablation [RFA]), as depicted in standard abdominal ultrasound imaging.

The streamed ultrasound images are captured and analyzed by the BioTraceIO algorithm, providing a visual display of the expected ablation zone, namely the Reference Ablation Zone (RAZ), calculated based on technical parameters provided by the ablation manufacturer datasheet. The RAZ is displayed during the procedure (Online Mode). BioTraceIO Precision also provides a visual display of the estimated ablation zone correlative to the 24-hour CECT, namely the BioTrace Map (BTM), after the completion of the procedure (Offline Mode).

Intended Use / Indications for Use

BioTraceIO Precision is intended to provide physicians with adjunctive information in their clinical assessment of ablation zone created by liver tissue ablation, as part of their overall post-procedure clinical assessment.

BioTraceIO Precision generates and depicts a map (BioTrace Map or BTM) post-procedure, that correlates with image findings seen with Contrast-enhanced Computed Tomography (CECT) obtained at 24hours post treatment. The information is provided in the 2D ultrasound plane. This is the only plane and location displayed. No imaging of other portions of the ablation zone is available.

During the ablation procedure BioTraceIO Precision overlays the reference ablation zone (RAZ) provided by the ablation device manufacturer on the ultrasound image.
BioTraceIO Precision is indicated for use in patients undergoing radiofrequency (RF) or microwave (MW) liver ablation procedures.

BioTraceIO Precision is not intended for standalone prediction or for diagnostic purposes.
BioTraceIO Precision does not support the use of multiple needles, either simultaneously or consecutively.

Manual ablation target contours and margins as defined by the user are not intended for diagnosis, to predict ablation volumes or predict ablation success.

The physician should not rely on BioTraceIO Precision BTM alone in decisions about patient management post treatment nor should BioTraceIO Precision serve as a substitute for any other assessment method, e.g., CT scans.

Summary of Technological Characteristics

Both the subject and predicate device are stand-alone software applications that use a proprietary computational algorithm to analyze ultrasound images captured during liver ablation treatment (microwave ablation [MWA] or radiofrequency ablation [RFA]), as depicted in standard abdominal ultrasound imaging.

The streamed ultrasound images are captured and analyzed by the BioTraceIO algorithm, providing a visual display of the expected ablation zone, namely the Reference Ablation Zone (RAZ), calculated based on technical parameters provided by the ablation manufacturer datasheet. The RAZ is displayed during the procedure (Online Mode). BioTraceIO Precision also provides a visual display of the estimated ablation zone correlative to the 24-hour CECT, namely the BioTrace

Map (BTM), after the completion of the procedure (Offline Mode).

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

The primary differences between devices are: (1) BTM algorithm processing time has been optimized to reduce delay for the user, and in turn is displayed in the offline mode 15 minutes after the ablation procedure has been completed (2) the RAZ algorithm has been adapted to have the same implementation used for BTM processing for the purpose of algorithm optimization and easier maintenance (3) user interface (UI) modifications have been made to improve the user experience
(4) cybersecurity improvements have been made (5) technical modifications have been made such as name change, file configuration change and architecture change.

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

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

	Subject Device **BioTraceIO Precision (Ver 2.0)**	**Predicate Device** **BioTraceIO Precision (previously commercially named BioTraceIO Lite)**
DeNovo/510(k) number	K243084	DEN230020
Classification	Class II QZL	Class II QZL
Intended Use	A stand-alone software application with tools and features designed to assist users in their clinical assessment of ablation zone created by liver tissue ablation, as part of their overall post-procedure clinical assessment.	A stand-alone software application with tools and features designed to assist users in their clinical assessment of ablation zone created by liver tissue ablation, as part of their overall post-procedure clinical assessment.
Indications for Use	BioTraceIO Precision is intended to provide physicians with adjunctive information in their clinical assessment of ablation zone created by liver tissue ablation, as part of their overall post-procedure clinical assessment. BioTraceIO Precision generates and depicts a map (BioTrace Map or BTM) post-procedure, that correlates with image findings seen with Contrast-enhanced Computed Tomography (CECT) obtained at 24 hours post treatment. The information is provided in the 2D ultrasound plane. This is the only plane and location displayed. No imaging of other portions of the ablation zone is available. During the ablation procedure BioTraceIO Precision overlays the reference ablation zone (RAZ) provided by the ablation device manufacturer on the ultrasound image. BioTraceIO Precision is indicated for use in patients undergoing radiofrequency (RF) or microwave (MW) liver ablation procedures. BioTraceIO Precision is not intended for standalone prediction or for diagnostic purposes. BioTraceIO Precision does not support the use of multiple	BioTraceIO Lite is intended to provide physicians with adjunctive information in their clinical assessment of ablation zone created by liver tissue ablation, as part of their overall post-procedure clinical assessment. BioTraceIO Lite generates and depicts a map (BioTrace Map or BTM) post-procedure, that correlates with image findings seen with Contrast-enhanced Computed Tomography (CECT) obtained at 24 hours post treatment. The information is provided in the 2D ultrasound plane. This is the only plane and location displayed. No imaging of other portions of the ablation zone is available. During the ablation procedure BioTraceIO Lite overlays the reference ablation zone (RAZ) provided by the ablation device manufacturer on the ultrasound image. BioTraceIO Lite is indicated for use in patients undergoing radiofrequency (RF) or microwave (MW) liver ablation procedures. BioTraceIO Lite is not intended for standalone prediction or for diagnostic purposes.

	needles, either simultaneously or consecutively. Manual ablation target contours and margins as defined by the user are not intended for diagnosis, to predict ablation volumes or predict ablation success. The physician should not rely on BioTraceIO Precision BTM alone in decisions about patient management post treatment nor should BioTraceIO Precision serve as a substitute for any other assessment method, e.g., CT scans.	BioTraceIO Lite does not support the use of multiple needles, either simultaneously or consecutively. The physician should not rely on BioTraceIO Lite BTM alone in decisions about patient management post treatment nor should BioTraceIO Lite serve as a substitute for any other assessment method, e.g., CT scans.
Primary Differences	(1) the BTM algorithm processing time has been optimized through enhancements in algorithm architecture to reduce delay for the user, and in turn is displayed in the offline mode 15 minutes after the ablation procedure has been completed (2) the RAZ algorithm has been updated to utilize the same architectural framework as the BTM algorithm. This adaptation facilitates optimization and simplifies maintenance (3) user interface (UI) modifications have been made to improve the user experience such as button layout improvements and allow for selection of a reference US frame for needle marking (4) cybersecurity improvements have been made such as encryption of PHI and installation responsibilities (5) technical modifications have been made such as name change, report viewer file configuration change and software framework architecture change.	NA
User Population	Qualified trained operators	Qualified trained operators
Where used	BioTraceIO Precision is designated for use in a clinical operating environment with compatible ultrasound and liver tissue ablation devices.	BioTraceIO Precision is designated for use in a clinical operating environment with compatible ultrasound and liver tissue ablation devices.
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
Technological Characteristics	BioTraceIO Precision is a software application that uses a proprietary computational algorithm to analyze ultrasound images captured during	BioTraceIO Precision is a software application that uses a proprietary computational algorithm to analyze ultrasound images captured during

	liver ablation treatment (microwave ablation [MWA] or radiofrequency ablation [RFA]), as depicted in standard abdominal ultrasound imaging. The streamed ultrasound images are captured and analyzed by the BioTraceIO algorithm, providing a visual display of the expected ablation zone, namely the Reference Ablation Zone (RAZ), calculated based on technical parameters provided by the ablation manufacturer datasheet. The RAZ is displayed, during the procedure (Online Mode). BioTraceIO Precision also provides a visual display of the estimated ablation zone correlative to the 24-hour CECT, namely the BioTrace Map (BTM) fifteen (15) minutes after the completion of the procedure (Offline Mode).	liver ablation treatment (microwave ablation [MWA] or radiofrequency ablation [RFA]), as depicted in standard abdominal ultrasound imaging. The streamed ultrasound images are captured and analyzed by the BioTraceIO algorithm, providing a visual display of the expected ablation zone, namely the Reference Ablation Zone (RAZ), calculated based on technical parameters provided by the ablation manufacturer datasheet. The RAZ is displayed, during the procedure (Online Mode). BioTraceIO Precision also provides a visual display of the estimated ablation zone correlative to the 24-hour CECT, namely the BioTrace Map (BTM), thirty (30) minutes after the completion of the procedure (Offline Mode).
	Color-coded display of scores reflecting image quality and reliability of the RAZ motion compensation displayed in the UI using a color-coded 5-point scale. These scores are computed based on objective metrics, and their purpose is to ensure the correct execution of the algorithms in the BioTraceIO Precision system.	Generation of scores reflecting image quality and reliability of the RAZ motion compensation which runs as background calculations within the software and is not visible to the user. These scores are computed based on objective metrics, and their purpose is to ensure the correct execution of the algorithms in the BioTraceIO Precision system.
	Manual contouring of ablation target on the reference US frame and display of the ablation margin as defined by the user around the contour. This feature was cleared in K240773.	NA
Design: Data Visualization	BTM on offline mode; RAZ on online mode	BTM on offline mode; RAZ on online mode
Design; Data Input	Used with a hardware streaming device that is connected to an ultrasound machine output, to capture input ultrasound images.	Used with a hardware streaming device that is connected to an ultrasound machine output, to capture input ultrasound images.
Design: Online Mode	In online mode, the BioTraceIO algorithm analyses the ultrasound images, and calculates a transformation matrix per frame. The transformation matrix defines the movement and orientation change between two frames and is used to transform the RAZ and register it to the ultrasound image.	In online mode, the BioTraceIO algorithm analyses the ultrasound images, and calculates a transformation matrix per frame. The transformation matrix defines the movement and orientation change between two frames and is used to transform the RAZ and register it to the ultrasound image.

	In offline mode, the BioTraceIO algorithm calculates the BTM as it is generated during the procedure. BTM calculations are based on the biological response of the tissue to heating and its appearance on ultrasound imaging.	In offline mode, the BioTraceIO algorithm calculates the BTM as it is generated during the procedure. BTM calculations are based on the biological response of the tissue to heating and its appearance on ultrasound imaging.
Design: Offline Mode	In offline mode, the BioTraceIO algorithm calculates the BTM as it is generated during the procedure. BTM calculations are based on the biological response of the tissue to heating and its appearance on ultrasound imaging.	In offline mode, the BioTraceIO algorithm calculates the BTM as it is generated during the procedure. BTM calculations are based on the biological response of the tissue to heating and its appearance on ultrasound imaging.

Performance Data

BioTraceIO Precision 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 functional and algorithmic testing demonstrate that BioTraceIO Precision meets the user needs and requirements of the device, which are considered to be substantially equivalent to those of the listed predicate device.

Algorithmic testing was performed on the BTM algorithm, to ensure that performance and accuracy was as expected. The validation analysis resulted in a mean DICE coefficient of 84.7 [95% CI: 83.07, 86.49] and 85.5 [95% CI: 83.63, 87.43] for the optimized BTM and predicate BTM, respectively, as compared to ablation zone visualized on the 24-hour post ablation CECT (T=24 CECT). This result was tested using both paired t-test ($p = 0.2408$), as well as Wilcoxon Signed-Rank test ($p = 0.11$). Both methodologies yielded similar non-significant p-values, indicating no significant differences in measurement of mean dice coefficients between the two algorithms. The optimized BTM also demonstrated a significantly (paired t-test $p < 0.0001$; Wilcoxon Signed-Rank $p < 0.0001$) higher mean DICE coefficient compared to T=0 CECT when both were compared to T=24 CECT, with a mean within-tumor difference of 7.9 [95% CI: 4.2, 11.7) in favor of the optimized BTM.

These results correspond to the intended use of the device in correlating with the ablation zone visualization on T=24 CECT and supports its clinical utility.

The mean DICE coefficient for BioTraceIO Precision BTM compared to T=24 CECT was not significantly lower than the mean DICE coefficient for BioTraceIO Lite BTM versus T=24 CECT. This result highlights that BioTraceIO Precision BTM demonstrates equivalent performance in correlation of ablation zone visualized on T=24 CECT compared to the predicate BTM.

Overall, the validation has successfully demonstrated that the optimized BTM demonstrates equivalent performance to the predicate BTM, and that it is safe and effective in estimating the area of ablation zone as visualized at 24-hour post procedure CECT scan.

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 version

of BioTraceIO Precision 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.

Conclusions

The BioTraceIO Precision (V2.0) is as safe and effective as the cleared BioTraceIO Precision (DEN230020). The BioTraceIO Precision has the same intended use, and principles of operation and similar technological characteristics 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 Precision and its predicate device raise no new issues of safety or effectiveness. Algorithmic testing demonstrates that the BioTraceIO Precision (V 2.0) is as safe and effective as the cleared BioTraceIO Precision (DEN230020). Thus, the BioTraceIO Precision is substantially equivalent to the predicate device.