TechsoMed Medical Technologies, Ltd.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia PA 19103

December 22, 2023

Re: DEN230020
Trade/Device Name: BioTraceIO Lite
Regulation Number: 21 CFR 892.2052
Regulation Name: Post-ablation tissue response prediction software
Regulatory Class: Class II
Product Code: QZL
Dated: March 30, 2023
Received: March 30, 2023

Dear Janice Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the BioTraceIO Lite, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> 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.
> 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the BioTraceIO Lite, and substantially equivalent devices of this generic type, into Class II under the generic name post-ablation tissue response prediction software.

FDA identifies this generic type of device as:

> **Post-ablation tissue response prediction software**. Post-ablation tissue response prediction software is an image processing software device intended to aid physicians with adjunctive information in their clinical assessment of the ablation zone following a tissue ablation procedure. This device uses information extracted from medical images along with other clinical data to predict the ablation zone post treatment.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 30, 2023, FDA received your De Novo requesting classification of the BioTraceIO Lite. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BioTraceIO Lite into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request and provided interactively in response to interactive deficiencies, FDA has determined that, for the previously stated indications for use, the BioTraceIO Lite can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Delayed patient care or additional unnecessary procedures due to software malfunction	Clinical performance testing Software verification, validation, and hazard analysis Labeling
Delayed patient care or additional unnecessary procedures due to incorrect output	Clinical performance testing Software verification, validation, and hazard analysis Labeling
Delayed or incorrect patient care due to misuse of information provided post procedure	Labeling

In combination with the general controls of the FD&C Act, the post-ablation tissue response prediction software is subject to the following special controls:

(1) Clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use and evaluate the following:
  (i) Ability to identify and visualize the ablation zone seen on images post treatment; and
  (ii) Accuracy in predicting the ablation zone post treatment.

(2) Software verification and validation must demonstrate device and algorithm functionality as informed by hazard analysis. Software documentation must include a detailed description of algorithm inputs and outputs, and any limitations of the algorithm.

(3) Labeling must include:
  (i) A detailed description of the user workflow; and
  (ii) A detailed summary of the clinical performance testing, including test methods, dataset characteristics, imaging modality/equipment, anatomical region, patient population specifying type and pathology of target tissue, target locations and sizes, and results.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the post-ablation tissue response prediction software they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Marjan Nabili at 240-402-3828.

Sincerely,

Robert Sauer for

Robert Ochs, Ph.D.
Director
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health