DE NOVO CLASSIFICATION REQUEST FOR BIOTRACEIO LITE

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 892.2052

CLASSIFICATION: Class II

PRODUCT CODE: QZL

BACKGROUND

DEVICE NAME: BioTraceIO Lite

SUBMISSION NUMBER: DEN230020

DATE DE NOVO RECEIVED: March 30, 2023

SPONSOR INFORMATION:

TechsoMed Medical Technologies, Ltd.
2 Meir Weisgal St.
Rehovot 7632605
Israel

INDICATIONS FOR USE

The BioTraceIO Lite is indicated as follows:

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.

LIMITATIONS

- The sale, distribution, and use of the BioTraceIO Lite are restricted to prescription use in accordance with 21 CFR 801.109.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

BioTraceIO Lite is a software application that uses a 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 (calculated based on technical parameters provided by the ablation manufacturer datasheet), namely the Reference Ablation Zone (RAZ), during the procedure (Online Mode - Figure 1).

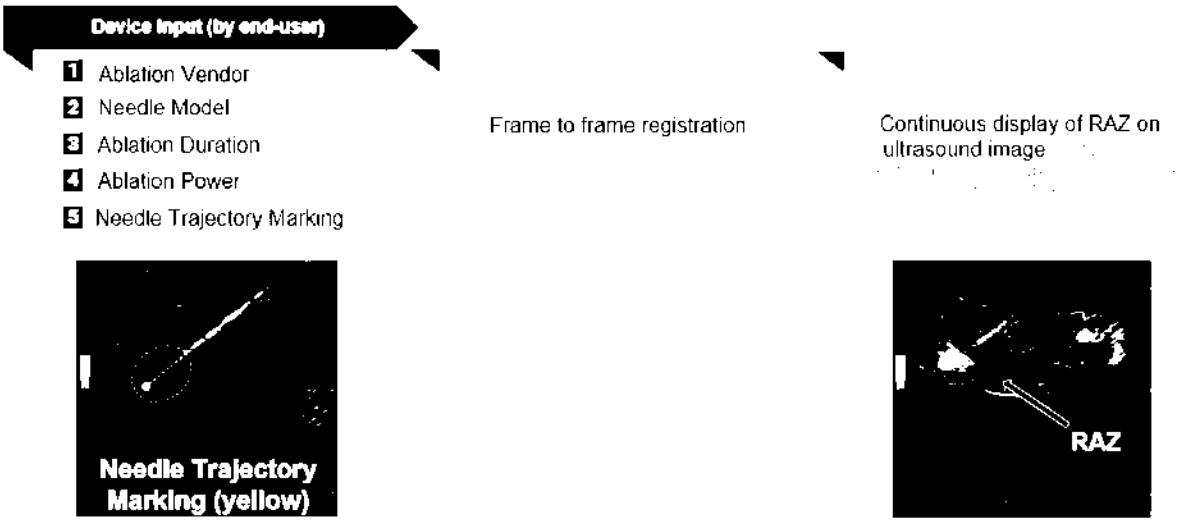

Figure 1. *Schematic of BioTraceIO Lite, as used in Online Mode*

Thirty (30) minutes after the completion of the procedure, BioTraceIO Lite provides a visual display of the estimated ablation zone correlative to the 24-hour CECT, namely the BioTrace Map (BTM) (Offline Mode - Figure 2).

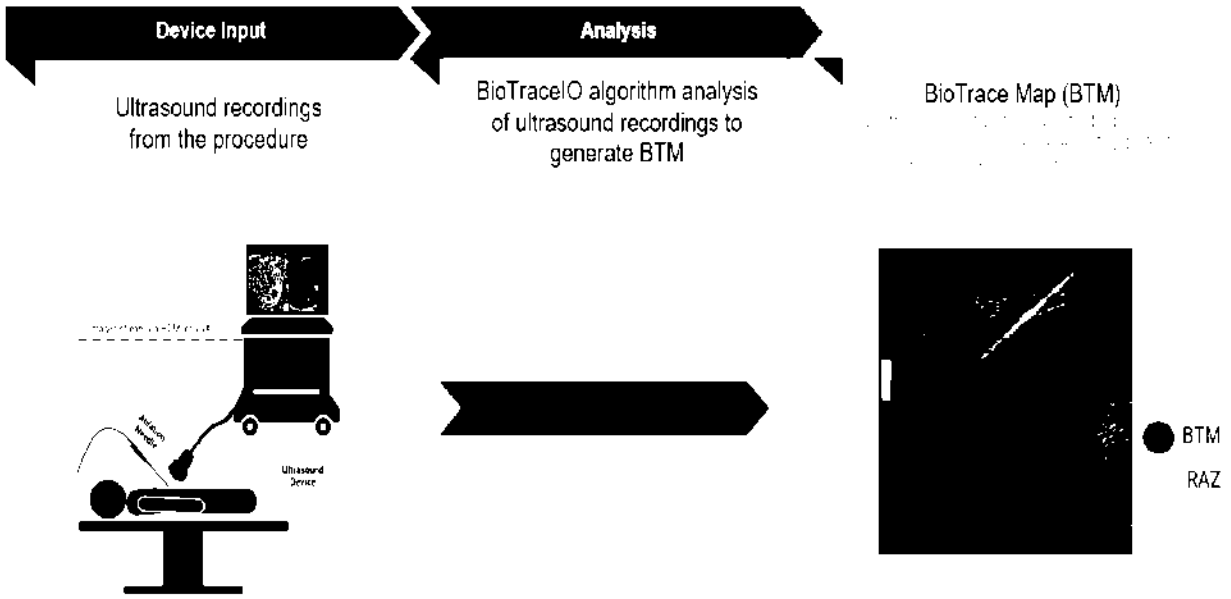

Figure 2. *Schematic of BioTraceIO Lite, as used in Offline Mode. Overlay of BTM (red) on processed ultrasound image*

Once in Offline Mode, it is not possible to return to Online Mode. The BTM is displayed only in Offline Mode, 30 minutes after the ablation procedure has been completed, and cannot be visualized in Online Mode, during the procedure.
Information from the ultrasound system streams in only one direction, to the BioTraceIO Lite software. BioTraceIO Lite utilized in either Online or Offline mode does not control or change the functions or parameters of the ultrasound system, or the ablation device used during the liver ablation procedure.

The BioTraceIO Lite application is installed on a dedicated, off-the-shelf, computer workstation with pre-defined minimal requirements and is controlled by the user via an independent user interface, which is separate from both the ablation system and the ultrasound system.
The workstation is connected by video output to a compatible ultrasound system to be used during the liver tumor ablation procedure. Specifications for compatible ultrasound systems are defined in Table 1:

Table 1: *Specifications for Compatible Ultrasound System*

Specification	**General Parameter**
Transducer type	Curved
Frequency	3-5 MHz
Gain	Maximal

Scan Line Density	High
Image Size/Screen Resolution	800×600, 960×720, 1024×768, 1920×1080
CNR	|X| > 3 dB
Dynamic Range	60-70 dB
Maximum Depth of Field	20 cm
Minimum Depth of Field	2 cm

Mechanism of Action

During ablation, in the presence of elevated temperatures, denatured tissues emit dissolved nitrogen, and microbubbles form. Once the gas microbubbles (also referred to as "bubbles") start to form within the heat-induced tissue, their continued formation and removal by the blood stream creates a unique traceable dynamic. The static and dynamic behavior of the gas microbubbles over time affects the spatial echogenicity of the ultrasound image throughout the ablation procedure. The BioTraceIO Lite algorithm performs automatic detection of dynamic gas bubble activity on each ultrasound frame in a single 2-D slice.

SUMMARY OF NONCLINICAL/BENCH STUDIES

Bench testing was conducted to demonstrate that BioTraceIO Lite performs as expected under the anticipated conditions of use. The following bench testing was conducted to demonstrate the device performance characteristics:

SOFTWARE AND CYBERSECURITY

The BioTraceIO Lite software documentation and testing provided demonstrate that the device meets all requirements outlined in the FDA "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" for software of moderate level of concern and Cybersecurity outlined in Section 524B of Federal Food, Drug, and Cosmetic Act (FD&C Act).

PERFORMANCE TESTING - ANIMAL

A preclinical study was conducted to evaluate the technical performance of the BioTraceIO algorithm during *in-vivo* percutaneous porcine liver microwave ablation procedure and to compare the BTM with the ablation zone visualized on the 24-hour post ablation CECT.

One pig was subjected to transcutaneous microwave ablation ([(b)(4)] Microwave Ablation System) using [(b)(4)] PR Probe, 15-19 cm, 17 gauge. Ablation was performed at the same power with varying ablation durations for each of the ablation cases and was monitored using a BK Flex Focus 800 ultrasound system. Twenty-four (24) hours following the ablation procedure, the pig was subjected to CECT and was euthanized immediately after the imaging procedure. The results of this study showed a

mean ratio of 93% (± 4.39 SD) between the BTM and the ablation zone visualized on the 24-hour post ablation CECT.

SUMMARY OF CLINICAL INFORMATION

Clinical Trial- Pivotal study

A multi-center prospective single-arm pivotal clinical study was performed to demonstrate the safety and effectiveness of BioTraceIO Lite for assessment of tissue ablation and predicting the ablated area following RF and Microwave liver tissue ablation procedures. The study was conducted at six clinical sites in the United States.

The overall objective of this study was to demonstrate the safety and effectiveness of BioTraceIO Lite by estimating whether the BTM, depicted immediately post ablation procedure in RF and Microwave liver ablation procedures, correlates to the ablation zone as visualized in 24-hour post-procedure (T=24) CECT scan. The current standard of care (SoC) is use of a CECT immediately following the ablation (T=0) only, with post-treatment and follow-up decisions based on the appearance of the ablated region immediately post-ablation. However, the ablation zone continues to change as time progress, therefore the T=0 CECT offers incomplete visualization of the size of the final ablation zone.

Primary effectiveness objective:
The primary effectiveness objective was to demonstrate that the BTM available post-procedure is correlative to the area of ablation zone as visualized on 24-hours post-procedure (T=24) CECT scan.

Primary safety objective:
The primary safety objective of this study was to demonstrate that the BioTraceIO Lite device is safe, based on an assessment of device-related Adverse Events (AEs) and serious adverse events (SAEs).

Study Endpoints

Primary Endpoints

- Effectiveness
  To demonstrate that the BTM available 30 minutes post-procedure is correlative to the area of ablation zone as visualized in 24-hour post-procedure (T=24) CECT scan.

- Safety
  Incidence and severity of device-related adverse events occurring from the beginning of the liver ablation procedure until the completion of the T=24 CECT.

Secondary Endpoints:

- Sensitivity and Precision of the BTM at T=0 compared to CECT at T=24.

- Directional Expansion Distance as detected by the BTM, in the same direction as the ablation zone visualized on 24-hour CECT maximal expansion distance.

Exploratory Endpoints:

- Comparison between ablation volume visualized at T=0 CECT the ablation volume visualized at T=24 CECT.
- The proportion of patients in whom the investigator indicated that, if the BTM was available for use in patient management, it would have impacted their follow-up plan for patient management, compared to the T=0 CECT alone (the standard of care).

Study Design

The primary endpoint was evaluated using a paired comparison of the Dice similarity coefficient, assessed between BTM, as measured at the end of the ablation procedure (from the oblique ultrasound plane that was monitored during the procedure), and the ablation zone based on 24 hours post-procedure CECT (T=24) (from the 2D CECT plane corresponding to the ultrasound oblique plane), and the Dice similarity coefficient, assessed between the ablation zone based on immediate post-procedure CECT (T=0) (from the 2D CECT plane corresponding to the ultrasound oblique plane) and the ablation zone based on 24 hours post-procedure CECT (T=24). For each patient and each pair of compared methods (i.e.: BTM vs T=24 CECT and T=0 vs. T=24 CECT) the area of ablation zone was overlaid.

The analysis of the imaging data acquired in the study (i.e., T=0 and T=24 CECT) was performed independently by certified interventional radiology experts, blinded to each other. The experts were trained on the CECT segmentation and registration processes specific to this study. During the study, the physicians were provided with questionnaires regarding RAZ and BTM benefits.

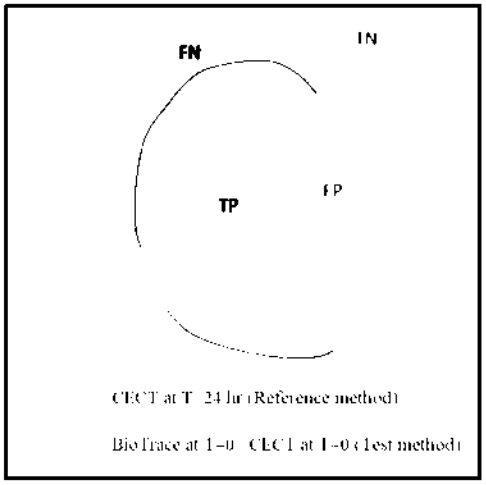

Figure 3. *Analysis method for comparing ablation zones.*

Based on the overlay of areas, as shown in Figure 3, the following values were defined:

1. True Positive (TP) was calculated based the number of pixels that overlap between T=24 CECT (blue area) and T=0 CECT (grey area).
2. False Negative (FN) was calculated based on the number of pixels that appear in the ablation zone visualized on T=24 CECT (blue area), but not in the ablation zone visualized on the T=0 CECT (grey area).
3. False Positive (FP) was calculated based on the number of pixels that do not appear either in the ablation zone visualized on T=24 CECT, nor that of the T=0 CECT.

Dice similarity coefficient was calculated using: $$\text{Dice} = \frac{2 \times \text{TP}}{\text{FN} + \text{FP} + 2 \times \text{TP}}$$

Sensitivity was calculated using: $$sensitivity = \frac{\text{TP}}{\text{TP} + \text{FN}}$$

Positive Predictive Value (PPV; Precision) was calculated using: $$PPV = \frac{TP}{\text{TP} + \text{FP}}$$

The analysis of the imaging data acquired in the study (i.e., T=0 and T=24 CECT) was performed independently by certified interventional radiology experts, blinded to each other. The experts were trained on the CECT segmentation and registration processes specific to this study. During the study, the physicians were provided with questionaries regarding RAZ and BTM benefits.

Directional Expansion Distance

BTM directional expansion distance was estimated in the direction of the maximal distance obtained between T=0 CECT and T=24 CECT contours. This distance is denoted as "True Expansion". The True Expansion was considered as the highest risk area (worst case scenario), where the recognizable ablation zone is the furthest from the contour of the T=0 CECT. Similarly, the distance between BTM and T=24 CECT contour was calculated in the direction of True Expansion, and the difference between this distance and the True Expansion was calculated.

The BioTrace Map max expansion can provide either complete match, over estimation or partial match as compared to the maximal difference seen between the ablation zone contour in T=0 CECT and that of T=24 CECT (True Expansion). In addition, the BioTrace map could show under estimation as compared to the ablation zone contour seen on T=0 CECT.

Sample size

Study flow chart below represents the number of subjects in the study. The study was powered to include 50 evaluable subjects. Subjects were considered evaluable for the primary effectiveness endpoint if they have completed ablation procedure, T=0 CECT, BTM calculation and T=24hrs CECT. If one of these elements is missing, the subject was deemed not evaluable. The results were calculated for 50 patients with 51 ablations.

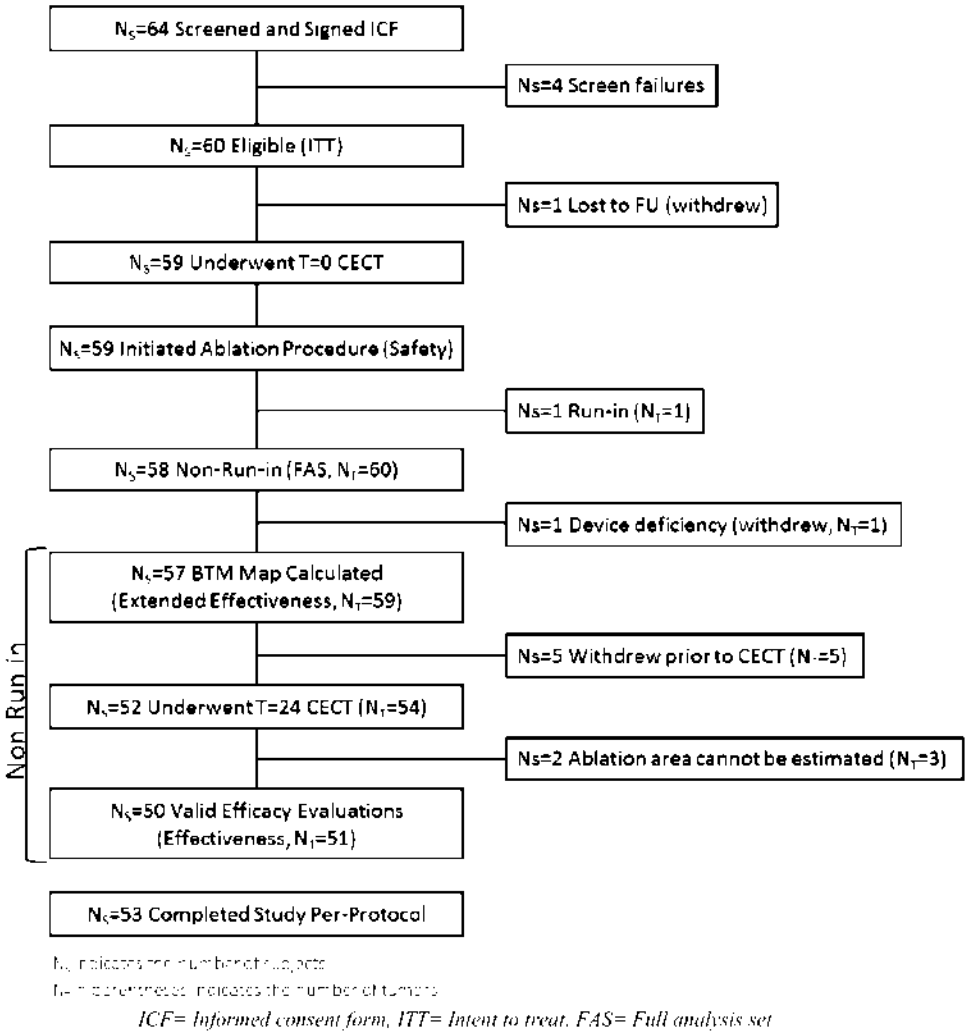

Figure 4. *Study Flow Chart.*

CECT at 24 hours post-procedure was not performed for 5 ablations in 5 patients. Of them, 3 patients with a total of 3 ablations terminated the study prior to post-procedure CT for different reasons. For the other 2 patients, within-procedure major protocol deviations occurred. Specifically, for 1 patient an unapproved ultrasound probe was used during the procedure; therefore, the patient was defined as ineligible and was not invited for the T=24 CECT. For another patient, an additional ablation was performed after repositioning of the needle which made this subject ineligible and the T=24 CECT was not performed. In addition, 2 patients with 3 ablations underwent T=24 CECT, but the results did not allow estimation of the ablation zone due to overlapping ablation zones, or bleeding. Thus, valid effectiveness results were calculated for 50 patients with 51 ablations.
Table 2-6 includes information on demographic characteristics, gender and race distribution, and liver and tumor characteristics of the study samples.

Descriptive statistics of patient age, height, weight, and BMI are presented in Table 2.

Table 2. *Descriptive Statistics of Demographic Characteristics*

Parameter	Mean	Std	Min	Median	Max	N
Age (years)	66.0	9.0	46.0	68.0	81.0	50
Height (cm)	171.0	35.0	140.0	173.0	188.0	50
Weight (kg)	88.6	27.9	46.2	88.0	141.8	50
BMI (kg/m2)	30.2	6.9	16.2	29.3	52.5	50

Patient gender and race are presented in Table 3.

Table 3*. Frequency Distribution of Gender and Race*

	Characteristic / Result	N	%	95% CI
Gender	Male	39	78.0	64.0 – 88.5
	Female	11	22.0	11.5 – 36.0
	Other	0	0.0	0.0-7.1
	Unknown	0	0.0	0.0-7.1
	All	50	100.0	
Race	American Indian or Alaska Native	0	0.0	0.0-7.1
	Asian	0	0.0	0.0-7.1
	Black or African American	2	4.0	0.5 – 13.7
	Native Hawaiian or Other Pacific Islander	0	0.0	0.0-7.1
	White or Caucasian	44	88.0	75.7 – 95.5
	Unknown or Not Reported	4	8.0	2.2 – 19.2
	All	50	100.0	

Liver and Tumor Characteristics

The number of patients with different liver and tumor conditions is summarized in Table .

Table 4*. Summary of Patient Liver and Tumor Characteristics*

Characteristic / Result		N	%	95% CI
Liver Condition	Healthy	11	22.0	11.5 – 36.0
	Fibrotic	2	4.0	0.5 – 13.7
	Cirrhotic	30	60.0	45.2 – 73.6
	Fatty	5	10.0	3.3 – 21.8

Characteristic / Result		N	%	95% CI
	Other	2	4.0	0.5 – 13.7
	All	50	100.0	
		N_T*	%	
Type of Liver Tumor	Primary	33	64.7	50.1 – 77.6
	Metastatic	18	35.3	22.4 – 49.9
	All	51	100.0	

Tumor location (liver segment) is specified in Table 5.

Table 5. *Frequency Distribution of Liver Tumor Location (live segment)*

Tumor Location (liver segment)	N_T*	%	95% CI
2	7	13.7	5.7 – 26.3
3	3	5.88	1.2 – 16.2
4a/b	2	3.9	0.4 – 13.5
5	11	21.6	11.3 – 35.3
6	8	15.7	7.0 – 28.6
7	12	23.5	12.8 – 37.5
8	8	15.7	7.0 – 28.6
All	51	100.0	

* N_T refers to the number of tumors / ablations

Tumor diagonal is described in Table 6.

Table 6. *Descriptive Statistics of Liver Tumor Diagonal*

Tumor Diagonal (mm)					
Mean	Std	Min	Median	Max	N_T*
18.0	6.38	1.0	17.0	30.0	51

* N_T refers to the number of tumors / ablations

Study Results

Primary Endpoint

The study demonstrated that the mean Dice coefficient for BTM compared to T=24 CECT was significantly higher than the mean Dice coefficient for T=0 CECT versus T=24 CECT (Table 7). This result highlights that BTM provides additional meaningful information that is correlative to the ablation zone visualized on T=24 CECT as compared to T=0 CECT.

Table 7: *Descriptive Statistics Significant Tests for Dice Coefficient (Effectiveness Analysis Set)*

Method	Mean	SD	Min	Median	Max	Lower 95% CL	Upper 95% CL	N_T*	Paired T-Test** P-Value	Wilcoxon** P-Value
DICE BTM vs T=24 CECT	85.5	6.8	56.0	87.0	94.0	83.6	87.4	51	<.0001	<.0001
DICE T=0 CECT vs T=24 CECT	76.8	12.7	10.0	80.0	88.0	73.2	80.3	51		

* N_T refers to the number of tumors / ablations

** 50 patients contributed 51 ablations in which only 1 out of 50 patients had 2 ablations and the remaining 49 patient had a single ablation in the data analysis. The correlation between outcome measures from the same subject was ignored in the data analysis due to the low number of subjects that contribute more than one ablation.

The primary safety endpoint was device-related adverse events occurring within 24 hours of the procedure. Out of 59 patients included in the Safety analysis set, 4 patients (5.1%) experienced a treatment-emergent adverse event (AE) during or after the day of the procedure. These included a closed fracture of the proximal end of right humerus, generalized muscle pain and pain in right upper abdomen. One patient experienced a treatment-emerged serious AE of intraparenchymal hematoma. None of these events was considered related to the BioTraceIO Lite. No serious or major adverse events related to the use of BioTraceIO Lite has been reported in this study.

Secondary Endpoints

In addition to the primary endpoint, the BTM sensitivity was found to be higher than that of the T=0 CECT, with 81.6% versus 63.7%, compared to the T=24 CECT (Table 8).

Considering both accuracy parameters (sensitivity and PPV), the BTM yields an 18% improvement in sensitivity and 8.4% loss in PPV compared to T=0 CECT. This trade-off between sensitivity and PPV is acceptable because increased sensitivity of correctly identifying the extent of ablation expansion is of greater clinical importance than slight overestimation, given that therapeutic action would be informed by clinical symptoms and repeat imaging, if needed.

Table 8: *Descriptive Statistics of Sensitivity and PPV of BTM (Effectiveness Analysis Set)*

Parameter/Method***		Mean	SD	Min	Median	Max	Lower 95% CL	Upper 95% CL	N_T
Sensitivity	BTM vs T=24 CECT	81.6	11.0	39.0	84.0	95.0	78.6	84.7	51
	T=0 CECT vs T=24 CECT	63.7	13.2	5.0	67.0	79.0	60.0	67.4	51
PPV**	BTM vs T=24 CECT	91.2	5.3	79.0	90.0	100.0	89.7	92.7	51
	T=0 CECT vs T=24 CECT	99.6	0.8	96.0	100.0	100.0	99.4	99.9	51

* N_T refers to the number of tumors / ablations

** PPV = Positive Predictive Value

*** 50 patients contributed 51 ablations in which only 1 out of 50 patients had 2 ablations and the remaining 49 patient had a single ablation in the data analysis. The correlation between outcome measures from the same subject was ignored in the data analysis due to the low number of subjects that contribute more than one ablation.

The results of the BTM directional expansion distance were divided into two categories - results that provide additional information beyond the T=0 CECT, and results that do not provide additional information. The former category was further split into 3 subgroups - partial match to True Expansion (defined as the maximal distance between T=0 ablation zone contour and T=24 ablation zone contour), complete match to True Expansion and over-expansion compared to True Expansion.

The directional expansion results showed that for a total of 46 ablations out of 51 (90.2%) the BTM provided additional information compared to T=0 CECT.

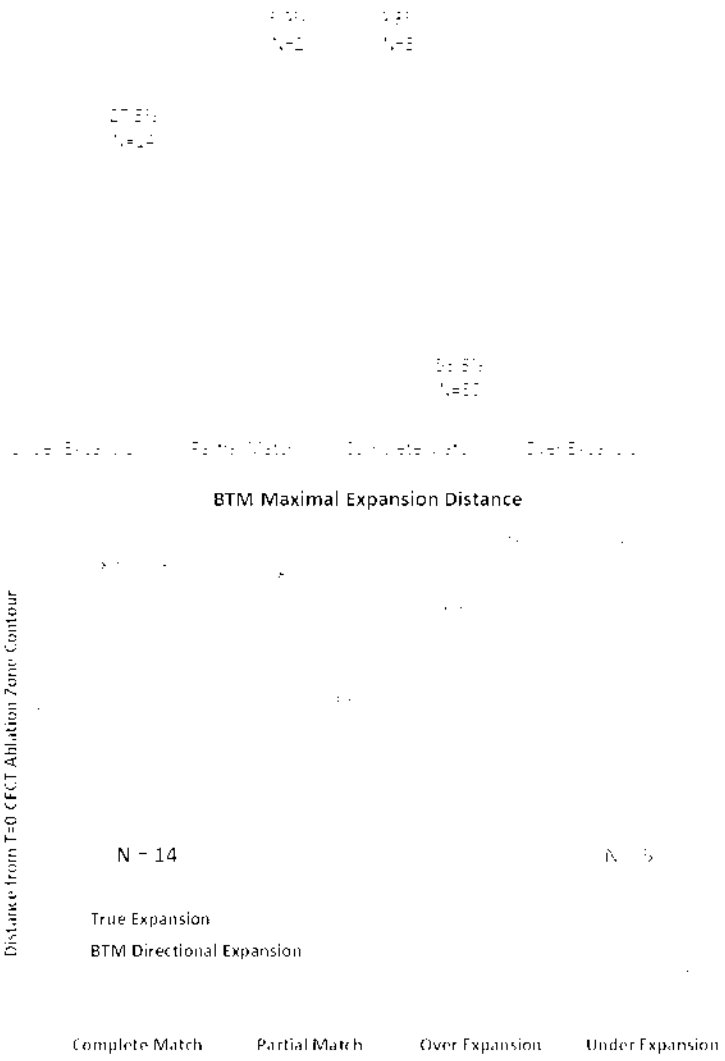

Figure 5. *Descriptive Statistics of BTM Directional Expansion (Effectiveness Analysis Set). True Expansion = Maximal distance from T=0 CECT ablation zone surface to T=24 CECT ablation zone surface; BTM Directional Expansion = Distance from T=0 CECT ablation zone surface to BTM surface.*

Exploratory Endpoints

Ablation volume comparison between T=0 CECT and T=24 CECT resulted in 41% differences (range: 23.8% - 62.7%) between the volumes (Table 9). These results demonstrate the ablation

volume growth between the end of the ablation procedure until 24 hours after it. The difference between the T=0 and T=24 CECT supports the need for an additional method that is available to estimate the expansion of the ablation within the first 24 hours. Together with the findings that in the majority of the ablations, the BTM provided additional information compared to T=0 CECT that partially or completely match the True Expansion, this further indicated that BTM could support predicting the ablation zone correlative to the 24-hour post ablation CECT.

Table 9. *Descriptive Statistics of Directional Expansion (Effectiveness Analysis Set)*

Method	Ablation volume (mL)					
	Mean	SD	Min	Median	Max	N
T=24 CECT	23.1	14.0	8.8	20.2	91.7	51
T=0 CECT	13.8	9.3	3.6	11.7	58.1	51
Difference	9.3	5.2	3.4	7.9	33.6	51
Percent Difference (%)	41.6	8.9	23.8	41.8	62.7	51

The answers from the questionnaires showed that all investigators across all study sites reported benefit from the RAZ visualization and registration, regardless of their expertise. The majority of investigators were positive regarding the visualization of the RAZ via ultrasound imaging during the procedure. When investigators were asked whether standard follow-up tests and follow-up appointment would be held as standard of care following the visualization of the BTM, for 16% of cases, the investigators indicated they would have changed the patient follow up (i.e., perform additional imaging, provide pain management medications or follow up more aggressively).

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling consists of Instructions for Use which include Indications for Use; description of the device; Contraindications; Warnings; Instructions on set up and user interface; Compatible ultrasound and computer workstation; a detailed summary of the clinical study in support of the device and the result; and an example of output report. The labeling meets the requirements of 21 CFR 801.109 for prescription devices.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of post-ablation tissue response prediction software and the measures necessary to mitigate these risks.

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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

The risks of the device are based on nonclinical and animal study as well as data collected in a clinical study described above. The probable risks of the device are: 1) delayed patient care or additional unnecessary procedures due to software malfunction, 2) delayed patient care or additional unnecessary procedures due to incorrect output, and 3) delayed or incorrect patient care due to misuse of information provided post procedure.

The probable benefits of the device are based on nonclinical laboratory and animal studies as well as data collected in a clinical study as described above. The current standard of care is use of a CT immediately following the ablation (T=0 CECT) only, with post-treatment and follow-up decisions based on the appearance of the ablated region immediately post-ablation.

BioTraceIO Lite provides important information on the likely appearance of the ablation zone 24 hours later, when it may have encroached on adjoining sensitive structures. The pivotal study demonstrated that the mean Dice coefficient for BTM compared to T=24 CECT was significantly higher than the mean Dice coefficient for T=0 CECT versus T=24 CECT. The BTM provides additional meaningful information that is correlative to the ablation zone visualized on T=24 CECT as compared to T=0 CECT. This permits a more nuanced approach to post-procedure follow-up.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> 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.

The probable benefits outweigh the probable risks for the BioTraceIO Lite. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the BioTraceIO Lite is granted and the device is classified as follows:

> Product Code: QZL
> Device Type: Post-ablation tissue response prediction software
> Regulation Number: 21 CFR 892.2052
> Class: II