MetriTrack, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

May 26, 2021

Re: K211098
Trade/Device Name: Breast Volume Navigator (BVN™) Model G-2000
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX, LLZ
Dated: May 11, 2021
Received: May 12, 2021

Dear Prithul Bom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211098

Device Name
Breast Volume Navigator (BVN™) Model G-2000

Indications for Use *(Describe)*
The Breast Volume Navigator (BVN) is an add-on accessory for existing ultrasound imaging systems and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2-dimensional image slices throughout a volume of interest. The BVN is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing.
The BVN is intended to assist health care providers trained in breast ultrasound with tools for electromagnetic tracking of instruments with respect of breast ultrasound images generated from FDA cleared hand-held ultrasound devices.
The BVN is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with a linear array transducer.

The BVN is indicated for use as an adjunct to hand-held breast ultrasound to assist the health care providers trained in breast ultrasound in their scanning process. The scanning paths are displayed on a route map and provide quality control of scanning to provide an overall observation of scanning process.
The BVN Software Application is intended as a standalone software device installed on a windows-based computer to assist physicians with manipulation and analysis tools in reviewing breast ultrasound images. Images and data are previously recorded from various imaging systems and other sources such as calibrated spatial positioning devices. The BVN Software Application provides the capability to visualize ultrasound images along with the scanning paths and position information of the probe that is stored in the DICOM file in advance.

The BVN will allow exporting to any third-party application that has the appropriate level of DICOM compliance.
The BVN is intended as a general-purpose digital 3D breast ultrasound image processing tool for radiology and surgery.

The device is not intended to be used in the environment of strong magnetic or electromagnetic fields, such as in Magnetic Resonance Imaging (MRI) room.
The device is not intended to be used as a replacement for screening mammography.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Number: K211098

Date Prepared:	February 5th, 2021
Manufacturer:	MetriTrack, Inc.
Address:	4415 W. Harrison Street, Suite 243 Hillside, IL 60162
Primary Contact Person:	Mirela Wohlford Director of Operations and Compliance MetriTrack, Inc. Tel. (708) 498-3578 Email: mirela@metritrack.com
Secondary Contact Person:	Calin Caluser CEO MetriTrack, Inc. Tel. (708) 498-3578 Email: calin@metritrack.com
Name of Device:	Breast Volume Navigator (BVN™) Model G-2000
Classification Name:	Ultrasonic pulsed echo imaging system
Classification Regulation:	21 CFR 892.1560 Ultrasonic pulsed echo imaging system 21 CFR 892.1570 Diagnostic ultrasonic transducer 21 CFR 892.2050 Medical image management and processing system
Classification Panel:	Radiology
Device Class:	II
Primary Product Code	IYO, ITX, LLZ

Predicate Devices:
Primary predicate: MetriTrack, LLC Breast Volume Navigator (BVN™) (K141870)
Reference device: TaiHao Medical Inc. BR-FHUS Navigation 1.0 (K171309)
Reference device: TaiHao Medical Inc. BR-FHUS Viewer (K171709)

Indications for Use / Intended Use: The Breast Volume Navigator (BVN™) is an add-on accessory for existing ultrasound imaging systems and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2-dimensional image slices throughout a volume of interest. The BVN™ is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing.

The BVN™ is intended to assist health care providers trained in breast ultrasound with tools for electromagnetic tracking of instruments with respect of breast ultrasound images generated from FDA cleared hand-held ultrasound devices.

The BVN™ is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with a linear array transducer.

The BVN™ is indicated for use as an adjunct to hand-held breast ultrasound to assist the health care providers trained in breast ultrasound in their scanning process. The scanning paths are displayed on a route map and provide quality control of scanning to provide an overall observation of scanning process.

The BVN™ Software Application is intended as a standalone software device installed on a windows-based computer to assist physicians with manipulation and analysis tools in reviewing breast ultrasound images. Images and data are previously recorded from various imaging systems and other sources such as calibrated spatial positioning devices. The BVN™ Software Application provides the capability to visualize ultrasound images along with the scanning paths and position information of the probe that is stored in the DICOM file in advance.

The BVN™ will allow exporting to any third-party application that has the appropriate level of DICOM compliance.

The BVN™ is intended as a general-purpose digital 3D breast ultrasound image processing tool for radiology and surgery.

The device is not intended to be used in the environment of strong magnetic or electromagnetic fields, such as in Magnetic Resonance Imaging (MRI) room.

The device is not intended to be used as a replacement for screening mammography.

Technological Characteristics

The Breast Volume Navigator (BVN™) Model G-2000, hereinafter maybe referred to as the BVN™ G-2000 System or the BVN™ System, comprises hardware components and a software element, including the following components: a magnetic position tracking device, sensor attaching pieces used to attach magnetic sensors to the skin and ultrasound probe, a central control unit computer, and software for controlling the system, collecting, and processing ultrasound images and positional data, and performing automated annotations.

The BVN™ System has a touch-screen user interface and push-button for power on the system.

The Use Interface (touchscreen display and central control unit computer) are placed on a medical grade cart that can be positioned next to a standard adjustable examination table for ease of use and ergonomic adaptation.

The BVN™ System has a USB port available for transferring files via USB Memory Stick.

The BVN™ System has an Ethernet port for connection to a PACS system, using DICOM.

The BVN™ System has a VGA/DVI Input Ports for capturing images from an ultrasound imaging scanner.

The BVN™ System receives ultrasound DICOM images from the US machine via the network connection and telemetry data from a position tracking system. The BVN™ automatically detects when the image is being frozen on the US machine and takes a snapshot of the telemetry data at that time. Later, when the BVN™ receives the DICOM image, it associates the telemetry data to the image from the time when the image was frozen on the US machine.

A Completeness-of-Scan Assessment ensures that all breast tissue has been sufficiently covered, the BVN™ System will achieve this by tracking the real-time position of the probe relative to the breast and chest wall to ensure the entire breast volume has been covered with sufficient detail to allow the detection of sub centimeter lesions. As the probe is swept over the breast region, the technician will be provided a completeness map highlighting the portions of the breast that have not been sufficiently scanned. The BVN™ System will provide the operator a display of regions with insufficient coverage, prompting the operator to rescan these regions. The BVN™ System can retrieve previous examinations DICOM images allowing the user to enter positional data from another/previous ultrasound examination for follow-up purposes. Any anomalies discovered during the follow-up process can be evaluated using the localization and measurement tools included in the software.

The customer's existing ultrasound probe securely attaches to the BVN™ System probe sensor. During a scan, the operator applies constant pressure to the transducer against the patient's breast tissue and can rotate the transducer (pitch and roll) to accommodate for the physical characteristics of the breast.

Exam data is subsequently reviewed on standard radiological viewing stations.

Pursuant to 809.92(a)(6), MetriTrack, Inc. claims that the Breast Volume Navigator (BVN™) Model G-2000 system is substantially equivalent to the devices previously cleared by FDA in K141871, K171309, and K171709 MetriTrack, Inc. claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principles, and physical and operational specifications compared to the predicate devices:

- It has the same intended use as the predicate devices (ultrasound image capture).
- It has the same technological characteristics as the predicate devices (use of magnetic sensors to track spatial relationships).
- The BVN™ System and the predicated devices listed above are accessories to an Ultrasonic Pulsed Echo Imaging System that have a Moderate Level of Concern.

The MetriTrack BVN™ G-2000 Software Application is Safety Class B according to ANSI/AAMI/IEC 62304 Ed. 1.1:2015 Medical device software - Software life cycle processes. Determination of the LOC and Safety Class is the result of risk assessment activities per ISO 14971. The Primary risks of the BVN™ G-2000 Software Application are related to the consequences of clinical decisions based on false positive and false negative results for a patient due to inaccurate result. For a false positive result, the risks could include unnecessary testing or inappropriate treatment related to an inaccurate result. For a false negative result, the risk could include a missed or delayed diagnosis, the following measures are intended to mitigate the risks and shall be communicated to the users:

1) The BVN™ G-2000 System is not intended to be used as the sole means for patient diagnosis or patient management decisions. The results should only be used in conjunction with the patient's clinical history.
2) All software-aided results must be reviewed and confirmed by a qualified physician. It is the responsibility of a qualified physician to employ appropriate procedures and safeguards to assure the validity of the interpretation of results obtained. No patient report can be created if the qualified physician does not confirm the result.

Further, MetriTrack, Inc. has determined that its device advances the field without deviating from the scope and spirit of the Act by enabling the user to visualize the ultrasound probe position and orientation over the patient's breast diagram in real time and perform automatic annotation in a stand-alone device that works with any standard ultrasound imaging system which have been previously cleared by FDA under the 510(k) process.

SUBSTANTIAL EQUIVALENCE CHART

Substantial Equivalence Parameters		MetriTrack - Breast Volume Navigator (BVN™G-2000) **Subject Device**	MetriTrack - Breast Volume Navigator (BVN™G-1000) – (K141870) **Predicate Device**	TaiHao Medical Inc. BR-FHUS Navigation 1.0 (K171309) **Reference Device**	BR-FHUS Viewer 1.0 (K171709) **Reference Device**
Regulation Number - Name	21 CFR 892.1560 - Ultrasonic Pulsed Echo Imaging System	**Yes**	**Yes**	**Yes**	**Yes**
	21 CFR 892.1570 Diagnostic ultrasonic transducer	**Yes**	**Yes**	**Yes**	No
	21 CFR 892.2050 Medical image management and processing system	**Yes**	No	No	**Yes**
Product Code	IYO	**Yes**	**Yes**	**Yes**	No
	ITX	**Yes**	**Yes**	**Yes**	No
	LLZ	**Yes**	No	No	**Yes**
Intended Use	The Breast Volume Navigator (BVN™) is an add-on accessory for existing ultrasound imaging systems and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2-dimensional image slices throughout a volume of interest. The BVN™ is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing.	**Yes**	**Yes**	No	No

Substantial Equivalence Parameters		MetriTrack - Breast Volume Navigator (BVN™G-2000) **Subject Device**	MetriTrack - Breast Volume Navigator (BVN™G-1000) – (K141870) **Predicate Device**	TaiHao Medical Inc. BR-FHUS Navigation 1.0 (K171309) **Reference Device**	BR-FHUS Viewer 1.0 (K171709) **Reference Device**
	The BVN™ is intended to assist health care providers trained in breast ultrasound with tools for electromagnetic tracking of instruments with respect of breast ultrasound images generated from FDA cleared handheld ultrasound devices.	**Yes**	**Yes**	**Yes**	No
	The BVN™ is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with a linear array transducer.	**Yes**	**Yes**	No	No
	The BVN™ is indicated for use as an adjunct to handheld breast ultrasound to assist the health care providers trained in breast ultrasound in their scanning process. The scanning paths are displayed on a route map and provide quality control of scanning to provide an overall observation of scanning process.	**Yes**	No	**Yes**	No
	The BVN™ Software Application is intended as a standalone software device	**Yes**	No	No	**Yes**

Substantial Equivalence Parameters		MetriTrack - Breast Volume Navigator (BVN™G-2000) **Subject Device**	MetriTrack - Breast Volume Navigator (BVN™G-1000) – (K141870) **Predicate Device**	TaiHao Medical Inc. BR-FHUS Navigation 1.0 (K171309) **Reference Device**	BR-FHUS Viewer 1.0 (K171709) **Reference Device**
	installed on a windows-based computer to assist physicians with manipulation and analysis tools in reviewing breast ultrasound images. Images and data are previously recorded from various imaging systems and other sources such as calibrated spatial positioning devices. The BVN™ Software Application provides the capability to visualize ultrasound images along with the scanning paths and position information of the probe that is stored in the DICOM file in advance.				
	The BVN™ will allow exporting to any third-party application that has the appropriate level of DICOM compliance.	**Yes**	**Yes**	No	No
	The BVN™ is intended as a general-purpose digital 3D breast ultrasound image processing tool for radiology and surgery.	**Yes**	**Yes**	No	No
	The device is not intended to be used in the environment of	**Yes**	**Yes**	**Yes**	No

Substantial Equivalence Parameters		MetriTrack - Breast Volume Navigator (BVN™G-2000) **Subject Device**	MetriTrack - Breast Volume Navigator (BVN™G-1000) – (K141870) **Predicate Device**	TaiHao Medical Inc. BR-FHUS Navigation 1.0 (K171309) **Reference Device**	BR-FHUS Viewer 1.0 (K171709) **Reference Device**
	strong magnetic or electromagnetic fields, such as in Magnetic Resonance Imaging (MRI) room.				
	The device is not intended to be used as a replacement for screening mammography.	**Yes**	**Yes**	No	No
Patient Population	This Device is intended to be used primarily upon female patients. This device is intended to be used on breast tissue.	**Yes**	**Yes**	No (Breast)	No (Breast)
Design	Accessory to System, Imaging, Pulsed Echo, Ultrasonic	**Yes**	**Yes**	**Yes**	No
	Ultrasonic Pulsed Echo Imaging System.	**Yes**	**Yes**	**Yes**	No
	Off-the-Shelf PC Computer	**Yes**	**Yes**	**Yes**	**Yes**
	Operating System: Windows	**Yes**	**Yes**	**Yes**	**Yes**
	Off-the-shelf Image Capture Device: USB frame grabber device connected to computer by cable	**Yes**	**Yes**	**Yes**	No

Substantial Equivalence Parameters		MetriTrack - Breast Volume Navigator (BVN™G-2000) **Subject Device**	MetriTrack - Breast Volume Navigator (BVN™G-1000) – (K141870) **Predicate Device**	TaiHao Medical Inc. BR-FHUS Navigation 1.0 (K171309) **Reference Device**	BR-FHUS Viewer 1.0 (K171709) **Reference Device**
	Using a magnetic position sensing unit to collect 3D spatial position information.	**Yes**	**Yes**	**Yes**	No
	Software: Position Sensor Monitoring, Image presentation and recording, user interface.	**Yes**	**Yes**	**Yes**	**Yes**
Where Used	Ultrasound examinations and procedures	**Yes**	**Yes**	**Yes**	**Yes**
End Users	Qualified medical imaging personnel that are familiar with traditional breast ultrasound procedures and techniques.	**Yes**	**Yes**	Skilled medical professionals	Skilled medical professionals
Performance Testing	Results from System verification and validation testing performed per internal procedures.	**Yes**	**Yes**	**Yes**	**Yes**

Electrical Testing

EMC testing per IEC 60601-1-2:2014 Class A, Group 2 for Emissions, Immunity for Professional Healthcare Facility Environment FCC Part 18.305:2020 and Electrical Safety Testing per NSI/AAMI ES60601-1 Edition 3.1 (revision 2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012). Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, technically the same as IEC 60601-1 with US National deviations) were performed for the BVN™ G-2000 System. All test results were acceptable for the BVN™G-2000 System.

Performance Data

Extensive Performance, Verification and Validation testing for the BVN™ G-2000 System was performed per internal procedures, which are compliant with 21 CFR Part 820.30, to ensure that all functional requirements have been met, and that core functions execute as expected.

Testing was conducted in-house by trained personnel in a simulated work-environment using phantoms to obtain the functional, accuracy and precision test results.

DESIGN VERIFICATION TESTS: The design specifications of the BVN™ G-2000 System were tested and verified to confirm that the product performance fulfilled those specification requirements.

DESIGN VALIDATION TESTS – NON-CLINICAL TESTING: System Validation testing was performed as follow:

1. Mapping the accuracy and precision of the BVN™ System position tracking capability within its sensing volume using a Volume Mapping Performance Test Phantom with 9 test locations and 3 layers above the test phantom, there layers were intended to cover the height of the operative volume which is 35 cm. In this environment the BVN™ System has achieved the following:
    - **Linear Accuracy and Linear Precision of Distance to Nipple:** accuracy and precision of ≤ 5 mm for measuring the distance of a target in a breast to nipple of the same breast.
    - **Accuracy and Precision of Clock Face Angle:** accuracy and precision of ≤ 5 degrees for measuring the Clock Face Angle of a target in a breast.
    - **Accuracy and Precision of Patient Body Angles:** accuracy and precision of ≤ 5 degrees for measuring the angles of the patient body relative to the examination bed in all three anatomical planes, i.e., Coronal, Transverse, and Sagittal planes.
    - **Accuracy and Precision of Linear Accuracy:** accuracy and precision of ≤ 1 mm for measuring the linear accuracy between two points in the ultrasound image at one standard deviation.
2. The completeness of scan accuracy has been tested using a Rigid Test Phantom to track the real-time position of the ultrasound probe relative to the region scanned to ensure that the entire scanning volume has been sufficiently scanned. In this environment the BVN™ System has achieved the following:

- **Completeness of Scanning Breast Contour Accuracy:** BVN™ accurately captured and represented the hand drawn breast contour with a maximum positional error of +/- 5 mm in the X-Y plane.
- **BVN™ correctly calculated the overlap between adjacent scanning bands and identified the occurrence of when this overlap is less than the set threshold as to ensure breast tissue is not missed between images:** BVN™ was able to discern when overlaps of adjacent bands are less than a set threshold within a range of 5 to 30 mm ± 2 mm of overlap.
- **3D Point Coordinates of Image Corners Velocity:** BVN™ detected 3D Point coordinates of image corners velocity above and below a set threshold within a range of 15 to 50 mm/s +/- 10% at 1 standard deviation as to ensure breast tissue is not missed between images.

Substantial Equivalence

The Breast Volume Navigator (BVN™) Model G-2000 is as safe and effective as the predicate devices: MetriTrack, LLC Breast Volume Navigator (BVN™) Model G-1000 (K141870), TaiHao Medical Inc. BR-FHUS Navigation 1.0 (K171309), and TaiHao Medical Inc. BR-FHUS Viewer (K171709). The minor technological differences between the Breast Volume Navigator and its predicate devices raise no new issues of safety and effectiveness.

Performance data demonstrate that the Breast Volume Navigator (BVN™) Model G-2000 is as safe and effective as its predicate devices.