QT Ultrasound LLC
Mark W. Lenox
Chief Technology Officer
3 Hamilton Landing, Suite 160
NOVATO, CA 94949

September 14, 2018

Re: K182213
Trade/Device Name: QT Ultrasound Breast Scanner - 1
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: August 14, 2018
Received: August 15, 2018

Dear Mark Lenox:

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.

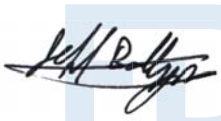
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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Date: 2018.09.14 13:52:52 -04'00'

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182213

Device Name
QT Ultrasound Breast Scanner - 1

Indications for Use *(Describe)*
The QT Ultrasound Breast Scanner - 1 is for use as an ultrasonic imaging system to provide reflection-mode and transmission-mode images of a patient's breast. 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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Diagnostic Ultrasound Indications for Use

System: QT Ultrasound Breast Scanner-1

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Breast)	N[1]						N[2]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N=New Indication; P = previously cleared by FDA; E = added under this appendix

1 – Reflection
2 – Transmission (Speed of Sound)
Additional Comments: QT Ultrasound Breast Scanner-1 is intended for ultrasonic breast exams

510(K) SUMMARY

In accordance with 21 CFR 807.92 the following summary of information is provided:

1.0 SUBMITTER INFORMATION

Submitted By	QT Ultrasound® LLC 3 Hamilton Landing, Suite 160 Novato, CA 94949
Contact Information	Mark W. Lenox, PhD Phone: (865) 382-2649 Fax: (415) 234-6511 Email: mark.lenox@qtultrasound.com
Date of Submission	September 12, 2018
Type of Submission	Special 510(k) Modification to QT Ultrasound Breast Scanner – 1(K162372)

2.0 DEVICE INFORMATION

Trade / Proprietary Name	QT Ultrasound Breast Scanner – 1
Common Name	System, Imaging, Pulsed Echo Ultrasonic Transducer, Ultrasonic, Diagnostic
Classification Name and Regulation Number	21CFR §892.1560 Ultrasonic pulsed echo imaging system 21CFR §892.1570 Diagnostic ultrasonic transducer
Product Codes	IYO, ITX

3.0 PREDICATE DEVICE

The predicate device is the QT Ultrasound Breast Scanner – 1, also manufactured by QT Ultrasound, LLC. QT Ultrasound Breast Scanner – 1 received market clearance under 510(k) number K162372.

4.0 DEVICE DESCRIPTION

The QT Ultrasound Breast Scanner – 1 is an automated software-controlled ultrasonic imaging system that performs a standardized scan of the whole breast. The QT Ultrasound Breast Scanner – 1 is comprised of a Patient Scanning System, Operator Console and Viewer Console.

The Patient Scanning System consists of a patient support table, scan tank, water management system, ultrasound transducer arrays and all associated image processing electronics. The scan tank is centered below a patient's breast and contains the ultrasound transducer arrays. The transducer arrays include a set of three reflection transducers that transmit pulsed ultrasound plane waves into targeted tissues using the water bath in the scan tank as a coupling medium. An additional transmitter and receiver array pair collect the ultrasound energy to provide speed of sound values.

During scanning, a patient lies prone on the examination table with the breast suspended in a warm water bath maintained near skin temperature. Images are automatically acquired on a pendant breast positioned with the nipple as a point of reference. The transducer arrays rotate about a vertical axis to circle the breast in the coronal plane. The array is then translated vertically, and the scanning process is repeated until the entire breast is scanned, allowing B-scan images to be constructively combined into tomographic, speed of sound and reflection ultrasound images.

The QT Ultrasound Breast Scanner – 1 outputs the images to the QTviewer™ which allows the images to be stored until they are reviewed on a Viewer Console. Coronal, axial and sagittal images are generated for review by the radiologist. Speed of sound images may be queried by the Probe and Region of Interest (ROI) tools provided in the Viewer Console. These tools provide speed of sound values in meters/sec. to aid in diagnostic evaluation of the breast.

5.0 INTENDED USE

The QT Ultrasound Breast Scanner – 1 is for use as an ultrasonic imaging system to provide reflection-mode and transmission-mode images of a patient's breast. The device is not intended to be used as a replacement for screening mammography.

6.0 PREDICATE DEVICE COMPARISON

The modified QT Ultrasound Breast Scanner – 1 is substantially equivalent to the predicate device, the QT Ultrasound Breast Scanner – 1 cleared by the FDA in K162372. QT Ultrasound claims substantial equivalence because the proposed device has an equivalent intended use, operating principles, fundamental scientific technology, technological characteristics, and physical and operational specifications as compared to

the predicate device. The modified QT Ultrasound Breast Scanner – 1 and the predicate device utilize B-mode grayscale ultrasound images to achieve their intended use. Both the modified QT Ultrasound Breast Scanner – 1 and the predicate device are table-top systems that have automatic scanning transducers to image breast tissue.

A brief summary of the similarities and differences between the modified QT Ultrasound Breast Scanner – 1 and the QT Ultrasound Breast Scanner – 1 (K162372) is included below:

Similarities

The fundament scientific technology and all Technological Characteristics are the same for both the modified QT Ultrasound Breast Scanner – 1 and the QT Ultrasound Breast Scanner – 1 (K162372); all technological characteristics and are listed below:

- Both systems use an automated transducer to acquire images of a patient's breast.
- Both systems use broadband transducers.
- Both systems acquire and process B-mode grayscale images of a patient's breast.
- Both systems acquire and process grayscale speed of sound images of a patient's breast.
- Both systems position the patient in a prone position lying on their examination table with the patient's breast in a pendulous position within an imaging chamber.
- Both systems position the patient's breast in a fluid environment to eliminate the need for breast compression and to facilitate the transmission of ultrasound waves.
- Both systems display of speed of sound Information is the same. Both provide grayscale speed of sound images that may be acquired by Probe and/or ROI tools available in the QTviewer. Both systems use this information as an aid/reference information for diagnostic evaluation of the breast.
- Both systems display 3-D volume image acquisition.
- Both systems perform image reconstruction in 3-D.

Differences

The differences between the modified QT Ultrasound Breast Scanner – 1 and the QT Ultrasound Breast Scanner – 1 (K162372) are the modifications made to the QTviewer Software Module. The summary of the differences between the modified QT Ultrasound Breast Scanner – 1 and the QT Ultrasound Breast Scanner – 1 (K162372) are listed in **Table 2-1**.

Table 2-1. Differences Between the Modified QT Ultrasound Breast Scanner – 1 and the QT Ultrasound Breast Scanner – 1 (K162372)	
Modification	**Discussion**
Modified QTviewer Software Module	Various bug fixes, cosmetic changes, addition of annotation features, snapshot feature and research mode, along with enhancements were made to the QTviewer Software Module that was part of the FDA cleared QT Ultrasound Breast Scanner – 1 (K162372).

The differences noted between the modified QT Ultrasound Breast Scanner – 1 and the predicate device, the QT Ultrasound Breast Scanner – 1 (K162372), do not present any new or different questions related to safety and effectiveness.

7.0 SUMMARY OF NON-CLINICAL TESTING

The function and performance of the modified QT Ultrasound Breast Scanner – 1 has been evaluated through non-clinical design verification and validation testing. All necessary testing was conducted on the proposed QT Ultrasound Breast Scanner – 1 to support a determination of substantial equivalence to the unmodified predicate device. Specifically, the impacts of the design changes presented with the subject device were evaluated through Design Control, and a number of required testing accordingly determined and subsequently performed. Testing included system performance and simulated use tests. When applicable, non-clinical testing was conducted per the standards listed in **Table 2-2**. All necessary validation testing, including comprehensive software verification and validation, was performed, the results of which demonstrate that the modified QT Ultrasound Brast Scanner – 1 successfully meets design specification. As a part of design validation, a small usability investigation was conducted, which demonstrated the new user interface presented with Reseach Mode meets user requirements.

This testing confirms that the design changes presented with the subject device do not raise new questions of safety and effectivess, the subject device meets design specifications, and that the subject and predicate devices are substantially equivalent. The modified QT Ultrasound Breast Scanner – 1 is only different due to an updated version of the QTviewer Software Module; therefore, not all testing was applicable since the original submission. A comparsion of all testing between the modified QT Ultrasound Breast Scanner – 1 and the predicate, QT Ultrasound Breast Scanner – 1 (K162372) is shown in **Table 2-2.**

Table 2-2. Testing Performed			
Type of Testing	**Tests Performed**	**QT Ultrasound Breast Scanner – 1 (K162372)**	**Modified QT Ultrasound Breast Scanner – 1 (This submission)**
Electrical Safety AAMI ES60601-1:2005/(R)2012 And A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	All applicable electrical, basic safety and essential performance tests. Testing was conducted by Intertek, an independent testing laboratory, located in Menlo Park, CA.	Performed	Not Applicable; the only modification made to the QT Ultrasound Breast Scanner – 1 is an updated QTviewer Software Module.
Electromagnetic Compatibility IEC 60601-1-2 Edition 3: 2007-03 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	All applicable testing pertaining to electromagnetic compatibility. Testing was conducted by Intertek, an independent testing laboratory, located in Menlo Park, CA.	Performed	Not Applicable; the only modification made to the QT Ultrasound Breast Scanner – 1 is an updated QTviewer Software Module.
Usability IEC 62366 Edition 1.1 2014-01 - Medical devices- Application of usability engineering to medical devices IEC 60601-1-6 Edition 3.1 2013-10 - Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability	All applicable testing pertaining to usability. Testing was conducted by Intertek, an independent testing laboratory, located in Menlo Park, CA.	Performed	Performed

Table 2-2. Testing Performed			
Type of Testing	**Tests Performed**	**QT Ultrasound Breast Scanner – 1 (K162372)**	**Modified QT Ultrasound Breast Scanner – 1 (This submission)**
Acoustic Output IEC 60601-2-37 Edition 2.0 2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment – Revision 3	All applicable testing pertaining to the requirements for the safety of ultrasonic medical diagnostic and monitoring equipment and to demonstrate compliance with the "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment". Testing was conducted by QT Ultrasound and witnessed by Intertek, an independent testing laboratory, located in Menlo Park, CA. The QT Ultrasound Breast Scanner – 1 meets all Track 1 acoustic output requirements. The results of acoustic output testing are listed in Table 2-3 below.	Performed	Not Applicable; the only modification made to the QT Ultrasound Breast Scanner – 1 is an updated QTviewer Software Module.
Software Development IEC 62304:2006 (First Edition) - Medical device software - Software life cycle processes	Internal procedures for software life cycle management were used for software development, verification / validation and configuration control	Performed	Not Applicable; the only modification made to the QT Ultrasound Breast Scanner – 1 is an updated viewer Software Module.

Table 2-2. Testing Performed			
Type of Testing	**Tests Performed**	**QT Ultrasound Breast Scanner – 1 (K162372)**	**Modified QT Ultrasound Breast Scanner – 1 (This submission)**
Software Verification and Validation	Software was tested at the module and system levels to ensure that it met the software's design and intended use requirements. All requirements were met, and no new issues of safety or effectiveness compared to the predicate device were raised.	Performed	Performed
System Verification and Performance	System verification testing was conducted to ensure that the QT Ultrasound Breast Scanner – 1 met design requirements. In addition, the following system performance characteristics are reported: • Measurement Range / Accuracy • Spatial Resolution • Contrast Resolution / Contrast to Noise Ratio • Speed of Sound Uniformity and Accuracy All requirements were met, and no new issues of safety or effectiveness compared to the predicate device were raised.	Performed	Not Applicable; the only modification made to the QT Ultrasound Breast Scanner – 1 is an updated QTviewer Software Module.

Table 2-2. Testing Performed			
Type of Testing	**Tests Performed**	**QT Ultrasound Breast Scanner – 1 (K162372)**	**Modified QT Ultrasound Breast Scanner – 1 (This submission)**
<u>Biocompatibility</u> ISO 10993-1:2009/(R)2013 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009/(R)2014 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010/(R)2014 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-11:2006/(R)2010 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Biocompatibility testing was conducted to ensure that the patient contacting materials in the QT Ultrasound Breast Scanner – 1 met design requirements. All requirements were met, and no new issues of safety or effectiveness compared to the predicate device were raised.	Performed	Not Applicable; the only modification made to the QT Ultrasound Breast Scanner – 1 is an updated QTviewer Software Module.
<u>Cleaning Procedures</u> Scan Tank	Microbial analysis and particulate testing of the water in the scan tank was conducted. All requirements were met, and no new issues of safety or effectiveness compared to the predicate device were raised.	Performed	Not Applicable; the only modification made to the QT Ultrasound Breast Scanner – 1 is an updated QTviewer Software Module.

8.0 SUMMARY OF CLINICAL TESTING

The modified QT Ultrasound Breast Scanner – 1 is a class II device, and has the same equivalent intended use, operating principles, fundamental scientific technology, technological characteristics, physical and operational specifications as predicate, QT Ultrasound Breast Scanner – 1 (K162372); clinical data is not required for substantial equivalence.

9.0 CONCLUSION

The submission device is a modification to the QT Ultrasound Breast Scanner – 1. The modified QT Ultrasound Breast Scanner – 1 is substantially equivalent to the QT Ultrasound Breast Scanner – 1 as previously cleared in K162372, with respect to intended use, principle of operation, design, performance, method of display and safety features. Both devices are intended as an adjunct to mammography and are not intended for screening purposes. The primary difference between modified device and the QT Ultrasound Breast Scanner – 1 (K162372) is the newer version of the QTviewer software.

QT Ultrasound has demonstrated through verification and validation testing that the modifications made to the QTviewer software as part of the QT Ultrasound Breast Scanner – 1 (K162372) do not raise new or different questions of safety and effectiveness. Therefore, it is the opinion of QT Ultrasound LLC that the modified QT Ultrasound Breast Scanner – 1 is substantially equivalent to the predicate device identified in this submission that is currently cleared for market in the United States.