QT Ultrasound, LLC
℅ Rajni Natesan, M.D., M.B.A.
Chief Medical Officer
3 Hamilton Landing, Suite 160
NOVATO CA 94949

October 18, 2019

Re: K190646
Trade/Device Name: QT Scanner 2000 Model A
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: September 4, 2019
Received: September 6, 2019

Dear Dr. Natesan:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190646

Device Name
QT Scanner 2000 Model A

Indications for Use *(Describe)*
The QT Scanner 2000 Model A 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)*

[X] 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.

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510(k) Notification K190646

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

QT Ultrasound LLC
3 Hamilton Landing Suite 160
Novato, CA 94949
Phone: 1-415-930-4070
Fax: 1-415-234-6511

Contact Person:

Rajni Natesan, M.D., M.B.A.
Chief Medical Officer
QT Ultrasound LLC
3 Hamilton Landing Suite 160
Novato, CA 94949
USA
Phone: 1-415-842-7244
Email: rajni.natesan@qtultrasound.com

Date Prepared: October 16, 2019

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

QT Scanner 2000 Model A

Generic/Common Name:

Ultrasonic pulsed echo imaging system

Classification:

21 CFR§892.1560, Ultrasonic Pulsed Echo Imaging System, Class II

Product Code:

IYO, ITX

PREDICATE DEVICES [807.92(a)(3)]

QT Ultrasound Breast Scanner-1 (K182213)

DEVICE DESCRIPTION [807.92(a)(4)]

The QT Scanner 2000 Model A ("QT Scanner") is an automated, software-controlled ultrasound imaging system which performs a standardized scan of the whole breast without the use of ionizing radiation, compression, or contrast injection; and generates both reflection-mode and transmission-mode breast images. The QT Scanner consists of a Patient Scanning System, an Operator Console, an optional offboard image processor, and the QTviewer software.

The Patient Scanning System contains the necessary electronics which perform acquisition and initial processing of the breast images and further provides a support table which allows the patient to rest comfortably while the scanning takes place. 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 Scanner outputs the images to a server which allows the images to be stored until they are reviewed on a Viewer Console running the QTviewer™ software. Alternatively, raw data files can be output to a server and remotely constructively combined into tomographic, speed of sound and reflection ultrasound images. Coronal, axial and sagittal images are generated for review by the radiologist. The QTviewer software also provides a number of analytics capabilities, such as biometric measurement, manual segmentation, and Region of Interest calculations.

INDICATIONS FOR USE [807.92(a)(5)]

The QT Scanner 2000 Model A 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

As the QT Scanner 2000 Model A is the technological successor to the Scanner-1 primary predicate device (K182213), the devices are highly consistent with respect to safety and technological characteristics. Both devices are automated diagnostic ultrasound imaging systems which perform a standardized scan of the whole breast in both reflection mode and transmission mode. Both devices share the same basic system layout and operational principles. There are a

few technological differences including the availability of additional processing methods and other minor technological enhancements which primarily represent routine parts upgrades (e.g., transducer elements, table shape, computer components, water management parts, electronic parts) and refinements in software parameters. The following table presents a high-level comparison of key technological aspects between the subject and predicate devices.

Feature	**Primary Predicate:** **QT Ultrasound LLC** **QT Ultrasound Breast Scanner-1** **(K182213)**	**Subject Device:** **QT Ultrasound LLC** **QT Scanner 2000 Model A** **(K190646)**
Classification	§892.1560 Ultrasonic pulsed echo imaging system Class II	§892.1560 Ultrasonic pulsed echo imaging system Class II
Product Code	IYO, ITX	IYO, ITX
Indications for 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.	The QT Scanner 2000 Model A 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.
Ultrasound Diagnostic Application	Small organ (breast)	Same
Ultrasound Track	Track 1	Same
Electrical Safety	AAMI ES60601-1:2005/(R)2012 And A1:2012	Same
Electromagnetic Compatibility	IEC 60601-1-2 Edition 3: 2007-03	IEC 60601-1-2 Edition 4: 2014-02
Acoustic Safety	IEC 60601-2-37 Edition 2.0 2007	IEC 60601-2-37 Edition 2.1 2015
Software Lifecycle Processes	In compliance with IEC 62304:2006	In compliance with IEC 62304:2015
Principles of Operation	• Reflection (B-Mode) and Transmission (Speed of Sound) Ultrasound • Displays 2D slice images and volume data • No compression – positions breast in pendulous position within a water bath	Same
Transducer Configuration	3 Reflection Mode , 1 Transmission Mode transmitter, and 1 Transmission Mode Receiver	Same basic configuration with updated transmission mode transducers and repositioned reflection mode transducers.
Global Maximum Acoustic Output Values	Max I_{SPTA}= 1.63 mW/cm^2	Max I_{SPTA}= 1.89 mW/cm^2
Imaging Modes	Acquires and processes B-mode (reflection) and speed of sound (transmission) images of a patient’s breast	Same

Feature	**Primary Predicate:** **QT Ultrasound LLC** **QT Ultrasound Breast Scanner-1** **(K182213)**	**Subject Device:** **QT Ultrasound LLC** **QT Scanner 2000 Model A** **(K190646)**
Image Processing Methods	• Single processing method All image processing/reprocessing are performed on the device	• General Processing • Implant Processing • Reprocessing: remove blur, artifacts, and dark spots All image processing/reprocessing can be performed on the device or on an offboard image processor
Image Output	Outputs DICOM images to a QTviewer workstation.	Same
Image Views	Coronal, axial, and sagittal	Same
Image Manipulation Functions	Full Screen Zoom Scroll Window/Level Window Level Presets Pan Gamma Invert, Flip, and Rotate	Same
Image Analysis Functions	Correlate Probe Region of Interest (ROI) Segment Linear Measurement Manual Annotation	Correlate Probe Region of Interest (ROI) Segment Linear Measurement Manual Annotation
Patient Position	Positions patient in the prone position on *flat* exam table with patient's breast in pendulous position within an imaging chamber	Positions patient in the prone position on *curved* exam table with patient's breast in pendulous position within an imaging chamber
Fluid Environment	Positions patient's breast in fluid environment to eliminate need for breast compression and facilitate transmission of ultrasound waves.	Same
Breast Positioning	Positions patient's breast by use of a patient positioning system comprised of breast insert ring, retention rod and device to align a patient's breast in imaging chamber	Same configuration with updated breast retention device design.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the QT Scanner 2000 Model A is substantially equivalent to the indications for use of the predicate devices. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the QT Scanner 2000 Model A is substantially equivalent to the predicate devices.

PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical performance testing was conducted on the QT Scanner 2000 Model A to support a determination of substantial equivalence to the predicate devices.

[807.92(b)(1)] Nonclinical Testing Summary:

The nonclinical, bench testing included:

- System Verification and Validation
- Software Verification and Validation
- Image Resolution Characterization
- Human Factors Testing
- Evaluation to the following standards:
    - ISO 10993-1:2009/(R)2013, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*
    - IEC 60601-1:2012, *Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance*
    - IEC 60601-1-2:2014, *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*
    - IEC 60601-2-37:2015, *Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*
    - IEC 60601-1-6:2013 - *Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability*
    - IEC 62304:2015, *Medical device software - Software life cycle processes*
    - IEC 62366:2014, *Medical devices- Application of usability engineering to medical devices*
    - NEMA UD 2-2004 (R2009), *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment – Revision 3*

The collective results of the nonclinical testing demonstrate that the QT Scanner 2000 Model A meets its designed specifications to support the acquisition, processing, display, and analysis of transmission- and reflection-mode breast ultrasound images; and support that the subject device does not raise different questions of safety or effectiveness for its intended use when compared to the predicate devices.

[807.92(b)(2)] Clinical Testing Summary:

The QT Scanner was evaluated clinically within three (3) retrospective clinical studies on previously-acquired QT Ultrasound breast images. Each study specifically evaluated a specific feature of the QT Scanner software which represented a technological difference against the predicate devices, as follows:

- The Implant Processing feature was validated through visual grade analysis in which three (3) expert radiologists independently reviewed 25 breast with silicone implant images selected by an image reconstruction expert. Each clinician user reviewed the reprocessed and default processed images in a blinded manner and comparatively evaluated the images with respect to overall interpretability and visualization of both implant-specific and general anatomical features. The study demonstrated that the Implant Processing feature provides superior overall interpretability of breast with silicone implant images, superior visualization of implant-specific anatomical features (i.e., implant center and implant-tissue interface), and non-inferior visualization of general anatomical features (e.g., nipple, skin).
- The transmission- and reflection- mode reprocessing features were validated through visual grade analysis in which three (3) expert radiologists independently reviewed 25 challenging-case breast images (13 dense breasts and 12 fatty breasts) selected by an image reconstruction expert. Each clinician user reviewed each reprocessed image compared to the default processed image in a blinded manner and comparatively evaluated the images with respect to overall speed-of-sound and reflection image diagnostic quality, as well as visualization of key anatomical features. The study demonstrated that the reprocessing method provides superior overall visualization of both speed-of-sound and reflection images, and provides at least non-inferior visualization of all relevant anatomical features.

The results of these clinical testing further validate the Implant Processing and Reprocessing features for their respective intended functions. As such, the clinical testing in conjunction with the results of nonclinical testing demonstrated that the QT Scanner is validated for its intended use, and that the subject device does not raise different questions of safety or effectiveness for its intended use when compared to the predicate devices.

CONCLUSIONS [807.92(b)(3)]

Performance testing of the QT Scanner supports that the subject device, like the Scanner-1 primary predicate device (K182213), can acquire, process, display, and analyze reflection- and transmission-mode ultrasound images of the breast. The minor differences in technology do not raise different questions of safety or effectiveness, and the QT Scanner is as safe and as effective for its intended use.

Thus, the results of performance testing support that the subject device is substantially equivalent to the predicate devices for its intended use.

SUMMARY

The QT Scanner 2000 Model A is substantially equivalent to the predicate devices.