QT Imaging, Inc.
℅ Mr. John Klock
CEO
3 Hamilton Landing, Suite 160
NOVATO CA 94949

August 31, 2022

Re: K220933
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, QIH
Dated: July 21, 2022
Received: July 22, 2022

Dear Mr. Klock:

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,

Julie Sullivan, Ph.D.
Acting Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*

K220933

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 QT Scanner 2000 Model A software also calculates the breast fibroglandular tissue volume (FGV) value and the ratio of FGV to total breast volume (TBV) value as determined from reflection-mode and transmission-mode ultrasound 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 indicated for use by trained healthcare professionals in environments where healthcare is provided to enable breast imaging in adult patients.

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.

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510(k) Notification K220933

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

QT Imaging, Inc.
3 Hamilton Landing Suite 160
Novato, CA 94949
Phone: 1-415-302-2048

Contact Person:

John Klock
Chief Executive Officer
QT Imaging, Inc
3 Hamilton Landing Suite 160
Novato, CA 94949
USA
Phone: 1-415-302-2048

Date Prepared: July 21, 2022

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
21 CFR§892.1570; Diagnostic Ultrasonic Transducer
21 CFR§892.2050; Medical Image Management and Processing System

Product Code:

IYO, ITX, QIH

PREDICATE DEVICES [807.92(a)(3)]

Primary predicate device: QT Ultrasound Breast Scanner-1 (K190646)
Reference device: syngo.via MI Workflows (K211459)

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. The QTviewer software also provides the "Fibroglandular Volume" (FGV) which is display of calculated fibroglandular tissue volume within a breast, expressed in dimensions of volume, as well as a ratio of the volume of fibroglandular tissue within the breast volume to the total breast volume, from QT Scanner breast images.

The QTviewer software also provides the "Fibroglandular Volume" (FGV) which is display of calculated fibroglandular tissue volume within a breast, expressed in dimensions of volume, as well as a ratio of the volume of fibroglandular tissue within the breast volume to the total breast volume (TBV), provided as FGV/TBV. The process for calculating FGV and FGV/TBV is based on image segmentation methods. The first step is segmentation of the whole breast from the surrounding water. Attenuation images are used to identify the boundary of the breast assuming that attenuation anywhere outside the breast (within water) is essentially zero. From skin inward, every pixel is labelled as breast tissue. The next step identifies the pixels in the vicinity of the boundary as border pixels and which constitute the skin of the breast. The pixels labelled as

surrounding water and skin are removed from the breast and the remaining breast volume is deemed as TBV. In the next step, pixel values from the segmented speed of sound image are provided to a one-dimensional fuzzy c-means (FCM) algorithm to partition of data set into two clusters: fibroglandular tissue and fat. Once FCM is trained, a membership map of fibroglandular tissue is generated and an empirically chosen threshold is applied to binarize the fibroglandular tissue membership map which constitutes fibroglandular tissue volume (FGV). The ratio of FGV to TBV (FGV/TBV) is then calculated by dividing the volume of the fibroglandular tissue by the volume of the whole breast.

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 QT Scanner 2000 Model A software also calculates the breast fibroglandular tissue volume (FGV) value and the ratio of FGV to total breast volume (TBV) value as determined from reflection-mode and transmission-mode ultrasound 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 indicated for use by trained healthcare professionals in environments where healthcare is provided to enable breast imaging in adult patients.

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

As the subject QT Scanner 2000 Model A is identical to the QT Scanner 2000 Model A primary predicate device (K190646), the devices are completely 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. The only technological difference is inclusion of the FGV and FGV/TBV feature within the QTviewer which is an imaging processing feature and the reference device for that feature is syngo.via MI Workflows (K211459). Please note that the table below is for comparison between the subject device and the primary predicate device. The only feature of the subject device for which the K211459 is used as a reference device is the image processing for calculation of FGV and TBV.

Feature	**Primary Predicate Device:** **QT Ultrasound LLC** **QT Scanner 2000 Model A** **(K190646)**	**Subject Device:** **QT Imaging, Inc.** **QT Scanner 2000 Model A** **(K220933)**
Classification	§892.1560 Ultrasonic pulsed echo imaging system §892.1570 Diagnostic ultrasonic transducer	§892.1560 Ultrasonic pulsed echo imaging system; §892.1570 Diagnostic ultrasonic transducer; §892.2050 Medical image management and processing system
Product Code	IYO, ITX	IYO, ITX, QIH
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 QT Scanner 2000 Model A software also calculates the breast fibroglandular tissue volume (FGV) value and the ratio of FGV to total breast volume (TBV) value as determined from reflection-mode and transmission-mode ultrasound 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 indicated for use by trained healthcare professionals in environments where healthcare is provided to enable breast imaging in adult patients.
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 4: 2014-02	Same
Acoustic Safety	IEC 60601-2-37 Edition 2.1 2015	Same
Software Lifecycle Processes	In compliance with IEC 62304:2015	Same

Feature	**Primary Predicate Device:** **QT Ultrasound LLC** **QT Scanner 2000 Model A** **(K190646)**	**Subject Device:** **QT Imaging, Inc.** **QT Scanner 2000 Model A** **(K220933)**
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
Global Maximum Acoustic Output Values	Max I_{SPTA}= 1.89 mW/cm^2	Same
Imaging Modes	Acquires and processes B-mode (reflection) and speed of sound (transmission) images of a patient's breast	Same
Image Processing Methods	• 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	Same
Image Output	Outputs DICOM images to a QTviewer workstation.	Same
Image Views	Coronal, axial, and sagittal	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 Fibroglandular Volume (FGV) Ratio of FGV to Total Breast Volume (TBV)
Patient Position	Positions patient in the prone position on exam table with patient's breast in pendulous position within an imaging chamber	Same
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

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the QT Scanner 2000 Model A is substantially equivalent to the indications for use of the primary predicate device. 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 primary predicate device.

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 primary predicate device.

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

The nonclinical, bench testing included:

- Software Verification and Validation

The testing that was done for the primary predicate device, QT Scanner 2000 Model A (K190646), and not done for the subject QT Scanner 2000 Model A included:

- System 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 primary predicate device.

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

The only technological difference between the subject and primary predicate device is the ability to calculate and display the fibroglandular volume (FGV and the ratio of FGV to total breast volume (TBV. To demonstrate this ability, a retrospective study was conducted where the FGV and FGV/TBV as determined from QT Scanner images were compared to the respective values as determined via breast MRI. Specifically, through a retrospective analysis of 53 breasts from 29 patients previously scanner on both QT Scanner and breast MRI, it was demonstrated that there is strong correlation between the respective values as determined by the two modalities.

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 primary predicate device.

CONCLUSIONS [807.92(b)(3)]

Performance testing of the QT Scanner supports that the subject device, like the primary predicate device (K190646), 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 primary predicate device for its intended use.

SUMMARY

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