March 04, 2026

QT Imaging Holdings, Inc.
Bilal Malik
Chief Science Officer
3 Hamilton Landing, Suite 160
NOVATO, CA 94949

Re: K253898
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: November 18, 2025
Received: December 5, 2025

Dear Bilal Malik:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MARJAN NABILI -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253898

Please provide the device trade name(s).

QT Scanner 2000 (Model A)

Please provide your Indications for Use below.

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 healthcareis provided to enable breast imaging in adult patients.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K253898

510(k) Notification K253898

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

QT Imaging Holdings, Inc.
3 Hamilton Landing Suite 160
Novato, CA 94949
Phone: 1-979-422-5573

Contact Person:
Bilal Malik, Ph.D.
Chief Science Officer
QT Imaging, Inc
3 Hamilton Landing Suite 160
Novato, CA 94949 USA
Phone: 1-979-422-5573

Date Prepared: March 3, 2026

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)]

QT Scanner 2000 Model A (K220933)

DEVICE DESCRIPTION [807.92(a)(4)]

The subject 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 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 generate images that 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.

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 PREDICATE DEVICE [807.92(a)(6)]

As the subject QT Scanner 2000 Model A is identical to the QT Scanner 2000 Model A 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.

Feature	**Predicate:** **QT Ultrasound LLC** **QT Scanner 2000 Model A** **(K220933)**	**Subject Device:** **QT Imaging, Inc.** **QT Scanner 2000 Model A** **(K253898)**
Classification	§892.1560 Ultrasonic pulsed echo imaging system Class II	§892.1560 Ultrasonic pulsed echo imaging system Class II
Product Code	IYO, ITX, QIH	IYO, ITX, QIH
Indications for Use	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.	Same
Ultrasound Diagnostic Application	Small organ (breast)	Same
Ultrasound Track	Track 1	Same
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 and Orientation	3 Reflection Mode, 1 Transmission Mode transmitter, and 1 Transmission Mode Receiver	Same configuration. The orientation of the transmission transmitter and receiver are tilted five degrees to improve incident field alignment.

Feature	**Predicate:** **QT Ultrasound LLC** **QT Scanner 2000 Model A** **(K220933)**	**Subject Device:** **QT Imaging, Inc.** **QT Scanner 2000 Model A** **(K253898)**
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	• General Processing • Implant Processing All image processing 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 Analysis Functions	Correlate Probe Region of Interest (ROI) Segment Linear Measurement Manual Annotation	Same
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 subject QT Scanner 2000 Model A is same as the indications for use of the predicate QT Scanner 2000 Model A device. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the subject QT Scanner 2000 Model A is substantially equivalent to the 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 predicate device.

The subject device, QT Scanner 2000 Model A, incorporates a software-only modification and no changes to patient-contacting materials, acoustic transmit characteristics, electrical construction, power distribution, enclosure, or mechanical assemblies. Biocompatibility remains supported by prior testing and risk assessment to ISO 10993-1:2009/(R)2013 (no change to materials, processing, or contact duration), therefore previous conclusions remain applicable. Electrical safety and essential performance were previously verified to IEC 60601-1:2012, and prior type-test results continue to apply. Electromagnetic compatibility was previously demonstrated to IEC 60601-1-2:2014; the modification does not change EMC-relevant hardware, cabling, or I/O characteristics, and software behavior does not introduce new emissions/immunity risks, so existing EMC evidence remains valid. Acoustic safety and performance were previously verified to IEC 60601-2-37:2015 and NEMA UD 2-2004 (R2009); the modification does not alter transmit timing, duty cycle, or output controls, and measured acoustic output limits and labeling remain unchanged, so prior acoustic data are applicable. Usability was addressed under IEC 60601-1-6:2013 and IEC 62366:2014; the modification does not introduce new user tasks or change critical task sequences, and formative/summative evaluations confirm unchanged use-related risk, thus existing usability evidence remains sufficient. Software lifecycle processes conform to IEC 62304:2015; the change was implemented under the established SDLC with updated hazard analysis, traceability, regression testing (including golden-dataset image reconstruction comparisons), and verification/validation showing identical clinical outputs and acceptance criteria relative to the cleared version. The collective results of the 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 device.

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

The clinical performance of the subject device was evaluated to confirm that the updated new processing option, for breasts without implants, does not impact its safety or effectiveness compared to the predicate device. Clinical testing performed via a visual grading analysis (VGA), performed to quantify the interpretation of image quality by a clinician, demonstrated that the image quality was improved with the updated processing option in comparison to the predicate device, without altering the core imaging capabilities or intended use of the device. No clinically significant differences were observed, supporting substantial equivalence to the predicate device.

As such, 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 device.

CONCLUSIONS [807.92(b)(3)]

Performance testing of the QT Scanner supports that the subject device, like the predicate device (K220933), 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 device for its intended use.

SUMMARY

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