DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

June 6, 2017

QT Ultrasound, LLC
% John C. Klock, M.D.
Chief Executive Officer and Managing Director
3 Hamilton Landing, Suite 160
NOVATO CA 94949

Re: K162372
Trade/Device Name: QT Ultrasound Breast Scanner-1
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: May 31, 2017
Received: June 1, 2017

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162372

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 OF SAFETY AND EFFECTIVENESS

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	John Klock, MD Phone: (415) 842-7242 Fax: (415) 234-6511 Email: john.klock@qtultrasound.com
Date of Submission	August 23, 2016
510(k) Number	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	90-IYO, 90-ITX

3.0 PREDICATE DEVICE

The predicate device is identified as the SoftVue System manufactured by Delphinus Medical Technologies. SoftVue received market clearance under 510(k) number K142517.

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 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 QT Ultrasound Breast Scanner-1 is substantially equivalent to the Delphinus Medical Technologies SoftVue System cleared by the FDA in K142517. QT Ultrasound claims

substantial equivalence because the proposed device has an equivalent intended use, operating principles, and physical and operational specifications as compared to the predicate device. The QT Ultrasound Breast Scanner - 1 and the predicate device utilize B-mode grayscale ultrasound images to achieve their intended use. Both the QT Ultrasound Breast Scanner-1 and the predicate SoftVue device are table-top systems that have automatic scanning transducers to image breast tissue.

The specific details regarding similarities and differences between the QT Ultrasound Breast Scanner-1 and the SoftVue device have been identified and explained in Comparison Tables provided in **Section 5.0** of this submission. A brief summary of the similarities and differences between the QT Ultrasound Breast Scanner-1 and the SoftVue device is included below.

Similarities

- 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 facilitate the transmission of ultrasound waves.

Differences

The differences between the QT Ultrasound Breast Scanner-1 and SoftVue System are listed in **Table 2-1**.

Table 2-1. Differences Between the QT Ultrasound Breast Scanner-1 and SoftVue System

Technological Characteristic	Discussion
Display of Speed of Sound Information	The QT Ultrasound Breast Scanner-1 provides grayscale speed of sound images that may be queried by the 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.
3-D volume Image Acquisition	Although, QT image acquisition is performed in 3D and SoftVue is acquired in 2D, this technological characteristic does not raise any

Table 2-1. Differences Between the QT Ultrasound Breast Scanner-1 and SoftVue System	
Technological Characteristic	**Discussion**
	different questions of safety and effectiveness compared to the predicate device.
Image Reconstruction	Although, QT image reconstruction is performed in 3D and SoftVue is reconstructed in 2D, this technological characteristic does not raise any different questions of safety and effectiveness compared to the predicate device.

The differences noted between the QT Ultrasound Breast Scanner-1 and the predicate device 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 QT Ultrasound Breast Scanner-1 has been evaluated through non-clinical design verification and validation testing. Testing included system performance and simulated use tests. When applicable, non-clinical testing was conducted per the standards listed in **Table 2-2**.

Table 2-2. Testing Performed	
Type of Testing	**Tests Performed**
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.
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.

Table 2-2. Testing Performed	
Type of Testing	**Tests Performed**
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.
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.
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
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.
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

Table 2-2. Testing Performed	
Type of Testing	**Tests Performed**
	All requirements were met and no new issues of safety or effectiveness compared to the predicate device were raised.
Biocompatibility 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.
Cleaning Procedures 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.

Acoustic output testing per IEC 60601-2-37 Edition 2.0 2007 was conducted by QT Ultrasound LLC and witnessed by Intertek, an independent testing laboratory, located in Menlo Park, California. 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**. A copy of the full test report is provided in **Section 6.0** of this submission.

Table 2-3. Global Maximum Acoustic Output Values						
Feature	**Track 1 Exposure Level**	**QT Ultrasound Breast Scanner-1 Level**				**Pass / Fail**
		Trans	**0**	**1**	**2**	
Max. Mechanical Index (MI)	1.9	0.145	.98	1.07	1.186	Pass
Max. I_{SPTA} (mW/cm^2)	94 mW/cm2	0.79	.713	0.995	1.63	Pass

The results of safety, performance and verification / validation testing demonstrate that the QT Ultrasound Breast Scanner-1 successfully meets the requirements of its intended use.

8.0 SUMMARY OF CLINICAL TESTING

VGA Review with QT Ultrasound vs. Xray Mammography (XRM)

QT Ultrasound LLC performed a Visual Grading Assessment (VGA) review of 22 cases from 20 subjects using four independent board-certified radiology readers. This was a paired-reader, paired-subject evaluation comparing the image quality of QT Ultrasound to X-ray mammography (XRM). The four readers independently scored the image quality of ten anatomical breast structures with XRM and QT Ultrasound during separate reading sessions, along with an overall image quality rating. The readers were provided the mammograms (CC and MLO views) and corresponding QT Ultrasound DICOM studies (Speed of Sound and Reflection images displayed in the coronal, axial, and sagittal planes) for each case.

VGA Review with QT Ultrasound vs. HandHeld Ultrasound (HHUS)

A similar VGA review of 17 cases was performed using 5 independent board-certified radiology readers. This was a paired-reader, paired-subject evaluation comparing the image quality of QT Ultrasound to HHUS. The five readers independently scored the image quality of ten anatomical breast structures with HHUS and QT Ultrasound during separate reading sessions, along with an overall image quality rating. The readers were provided the available targeted HHUS images (static DICOM images) and corresponding QT Ultrasound DICOM studies (Speed of Sound and Reflection images displayed in the coronal, axial, and sagittal planes) for each case.

The statistical analyses for both studies were performed under the direction of Nancy Obuchowski, PhD, Vice Chair of Quantitative Health Sciences at the Cleveland Clinic Foundation.

For the VGA study comparing QT Ultrasound and XRM, the results are as follows.

The median image quality score for each of the 10 anatomical features, as well as the overall image quality, was reported for each reader. The proportion of breasts where the image quality was rated better on QT Ultrasound than XRM or equivalent to XRM was reported for each feature. A 95% Confidence Interval (CI) for the proportion of breasts rated as equivalent or better image quality on QT Ultrasound was constructed for each feature using methods for clustered binary data, treating subject as the cluster. Similarly, the proportion of breasts where the image quality was rated better on QT Ultrasound than XRM was reported for each feature, along with its 95% CI.

Table 2-4. Median Image Quality Scores by Modality, Reader, and Feature (1=excellent, 5=poor)*

	QT Ultrasound				XRM			
Anatomical Feature	**R1**	**R2**	**R3**	**R4**	**R1**	**R2**	**R3**	**R4**
Skin (Overall)	1.5	1.0	1.0	2.0	2.0	4.0	3.0	2.0
Epidermis	1.0	1.0	1.0	1.0	2.0	4.0	2.0	1.0
Dermis	2.0	2.0	2.0	2.0	5.0	5.0	5.0	5.0
Hypodermis	2.0	1.0	1.0	1.0	3.0	4.0	2.0	1.0
Cooper's Ligament	1.5	1.0	1.0	1.0	4.0	4.0	4.0	4.0
Superficial Veins	2.0	1.0	1.0	2.0	3.5	4.0	4.0	4.0
Central Ducts Entering Nipple	2.0	2.0	2.0	3.0	3.5	5.0	4.5	4.0
Intermediate or peripheral Ducts	2.0	2.0	1.0	2.0	5.0	5.0	5.0	5.0
Terminal Duct Lobular Units	2.0	2.0	2.0	2.0	5.0	5.0	5.0	5.0
Pectoralis Muscle (Chest Wall)	3.0	4.0	3.0	3.0	3.0	2.0	2.0	2.0
Overall visualization of breast anatomy	2.0	2.0	1.0	2.0	4.0	4.0	4.0	4.0

* Ordinal Step Scale indicates how well the reader can see the anatomical breast structures. The definitions for the step scale are as follows:

1 = Excellent – No limitations

2 = Good – Minimal limitations

3 = Sufficient – Moderate limitations with no substantial loss of information

4 = Restricted – Relevant limitations with clear loss of information

5 = Poor – Significant loss of information

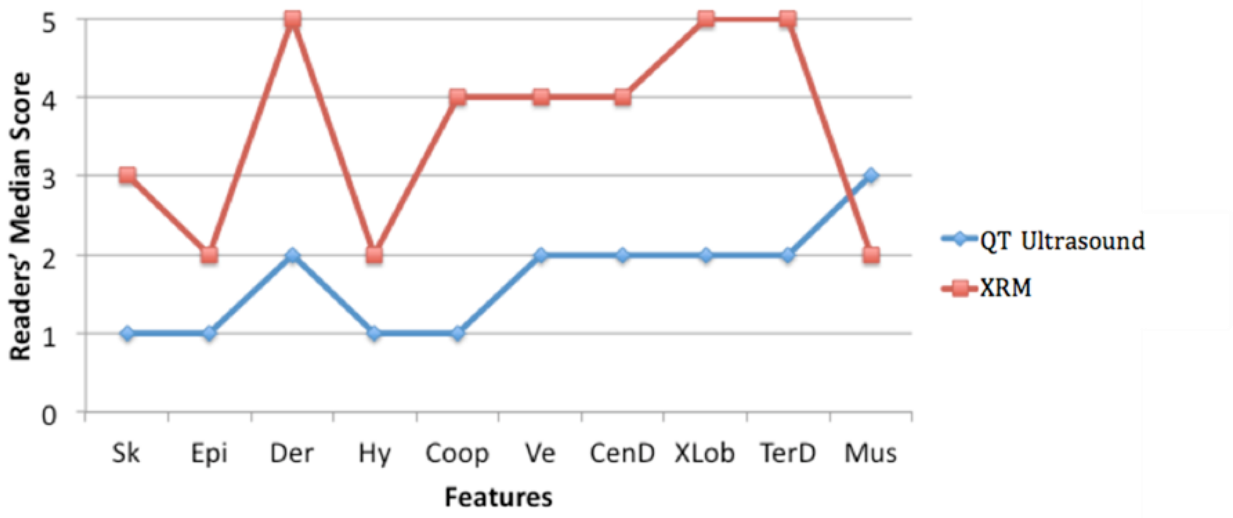

Figure 1: Readers' median image quality score by modality (QT Ultrasound in blue and XRM in red) and breast feature: skin (overall), epidermis, dermis, hypodermis, Cooper's ligaments, superficial veins, central ducts entering nipple, intermediate or peripheral ducts (extra-lobular ducts), terminal duct lobular units and pectoralis muscle (chest wall).

Image quality was scored on an ordinal rating scale: 1=Excellent, 2=Good, 3=Sufficient, 4=Restricted, 5=Poor.

The analysis of anatomical breast structures comparing QT Ultrasound images to XRM, demonstrated that the QT Ultrasound Breast Scanner-1 produces clinically-useful depictions of patient anatomy. The readers scored the image quality on the QT Ultrasound images as equivalent to or better than on XRM for each feature in more than 90% of breasts.

For the VGA review comparing QT Ultrasound vs. HHUS, the results are as follows:

Table 1 summarizes the median image quality scores from the results pooled over all readers, as well as the lowest median by any reader and highest median by any reader for each of the breast features. Note that readers used a score of 99 (i.e. anatomy not included on image) on both HHUS and QT Scan, but more often on HHUS. Figure 2 illustrates the readers' pooled median score for the two modalities. Except for epidermis where the median scores are equivalent, when the anatomy was visible on the image, the readers' median scores indicated superior image quality on the QT Scan.

Table 2-5: Median Image Quality Scores of 5 Readers by Modality and Feature						
	HHUS			**QTUS**		
	Median*	**Min****	**Max****	**Median***	**Min****	**Max****
Skin (Overall)	3.0 ***(80% not scored because not included on image)	3.0	3.0	2.0	1.0	2.0
Epidermis	1.0	1.0	2.0	1.0	1.0	2.0
Dermis	3.0	1.0	4.0	1.0	1.0	3.0
Hypodermis	2.0	1.0	3.0	1.0	1.0	2.0
Cooper's Ligament	3.0	2.0	4.0	1.0	1.0	1.0
Superficial Vessels	5.0 (18.8% not scored because not included on image)	2.0	5.0	1.0	1.0	2.0
Central Ducts Entering Nipple	5.0 ***(68.2% not scored because not included on image)	2.0	5.0	2.0	1.0	5.0
Intermediate or peripheral Ducts	5.0 (23.5% not scored because not included on image)	1.0	5.0	2.0	1.0	5.0
Terminal Duct Lobular Units	5.0 (21.2% not scored because not included on image)	4.0	5.0	2.0 (3.5% not scored because not included on image)	1.0	3.0
	Median*	**Min****	**Max****	**Median***	**Min****	**Max****
Pectoralis Muscle (Chest Wall)	3.0 (7.1% not scored because not included on image)	3.0	5.0	2.0 (8.2% not scored because not included on image)	1.0	4.0
Overall visualization of breast anatomy	3.0 ***(61.2% not scored because not included on image)	*3.0*	*4.0*	*2.0*	*1.0*	*3.0*

* median over 85 observations pooled from 5 readers
** minimum and maximum median of the 5 readers
****For HHUS, overall skin, central ducts and overall visualization of breast anatomy are features that have a majority of cases not scored due to targeted HHUS.*

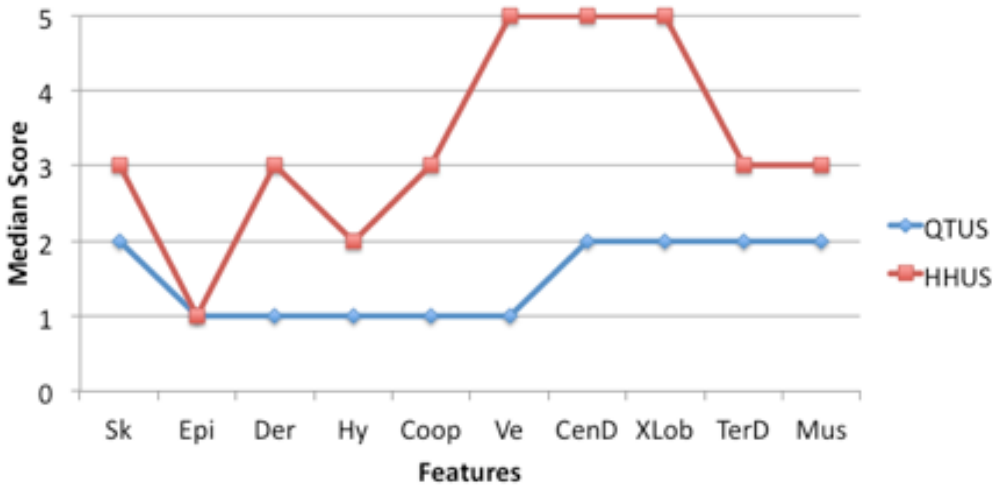

Figure 2: Readers' median image quality score by modality (QT Scan in blue and HHUS in red) and breast feature: overall skin (SK), epidermis (Epi), dermis (Der), hypodermis (Hy), Cooper's ligaments (Coop), superficial vessels (Ve), central ducts entering nipple (CenD), intermediate or peripheral ducts (XLob), terminal duct lobular units(TerD), and pectoralis muscle (Mus).

Image quality was scored on an ordinal rating scale: 1=Excellent, 2=Good, 3=Sufficient, 4=Restricted, 5=Poor.

Except for epidermis and pectoralis muscle, the readers scored the image quality on the QT Scan as equivalent or better than HHUS on each feature in more than 80% of breasts. Readers scored the image quality of epidermis and muscle as better on the QT Scan in more than 70% of breasts. On this initial study utilizing historical QT Library cases, the findings from the 5 study readers suggest that QT images are at least equivalent or better in defining the anatomical components of the breast than HHUS.

Representative Clinical Cases

Sixteen clinical cases of QT Ultrasound images representative of different breast densities and lesion types, such as cancer in fatty breast, cancer in dense breast and cyst in fatty breast, were reviewed by board certified radiologist, Dr. Elaine Iuanow, M.D. and Chief Medical Officer. There was no grading performed on the Representative Clinical Cases. The cases were representative of the different types of cases seen in the clinical setting. Each case, consisting of Mammography, Hand Held Ultrasound and QT Ultrasound imaging, for each subject was reviewed.

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The QT Ultrasound images were displayed in two modes, Speed of Sound (Transmission) and B-Mode (Reflection) images. Each imaging mode included coronal, axial and sagittal views. The cases included the span of clinical scenarios that the device would typically be used for.

The breast density patterns include fatty, scattered, heterogeneously dense and extremely dense. The density was determined by visual inspection on the QT Ultrasound images. The clinical history for each case was provided. Clinical information, such as previous biopsies and/or imaging studies were used to confirm the identification of lesions in the QT Ultrasound images using clock position, appearance, size and location. The speed of sound values for any identified lesions were also provided. The lesion type was determined by histology (ground truth) for solid benign and solid malignant lesions. The ground truth for cyst lesions was determined by its appearance on handheld ultrasound (HHUS).

Table 2-6. Case summary by breast density and lesion type

Case #	Case ID	Breast Density Determined Visually	Lesion Type
1	901-065-L	Extremely Dense	Solid-Benign
2	102007V	Heterogeneously Dense	*
3	901-005-L	Fatty	Cyst
4	102019V	Fatty	*
5	901-020-R	Scattered	Cyst
6	901-022-L	Scattered	Cyst
7	901-008-R	Heterogeneously Dense	Cyst
8	901-037-L	Scattered	Solid-Benign
9	901-043-L	Heterogeneously Dense	Solid-Malignant
10	901-044-L	Heterogeneously Dense	Solid-Malignant
11	901-001-L	Scattered	Cyst
12	901-029-R	Heterogeneously Dense	Cyst
13	901-041-L	Fatty	Solid-Malignant
14	901-019-R	Extremely Dense	Cyst
15	102002V	Fatty	*
16	901-034-R	Scattered	Solid-Benign

***** No lesion types are provided for volunteers as they were scanned for training only.

The clinical cases demonstrated the QT Ultrasound Breast Scanner-1 is capable of imaging different breast densities and lesion types over the span of clinical scenarios that the device would typically be used for.

9.0 CONCLUSION

The QT Ultrasound Breast Scanner-1 is substantially equivalent to the Delphinus SoftVue System with respect to intended use, principle of operation, design, performance and safety features. Both devices are intended as an adjunct to mammography and are not intended for screening purposes. The primary difference between the QT Ultrasound Breast Scanner-1 and the SoftVue System is the manner in which the qualitative speed of sound information is displayed. Although the method of display is different, the fundamental intended use is the same.

QT Ultrasound has demonstrated through verification and validation testing that the different technological characteristics between the SoftVue device and the QT Ultrasound Breast Scanner-1 do not raise new or different questions of safety and effectiveness. Therefore, it is the opinion of QT Ultrasound LLC that the 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.