DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 31, 2014

Delphinus Medical Technologies, Inc.
% Ms. Andrea Wallen-Gerding
Director of Quality & Regulatory Affairs
46701 Commerce Center Drive
PLYMOUTH MI 48170

Re: K142517
Trade/Device Name: SoftVue
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: September 10, 2014
Received: September 11, 2014

Dear Ms. Wallen-Gerding:

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

Janine M. Morris
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)*

K142517

Device Name
SoftVue

Indications for Use *(Describe)*

SoftVue™ is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning curvilinear array transducer. 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Diagnostic Ultrasound Indications for Use

System: SoftVue

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 (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Breast)	P						
	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	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments: SoftVue is intended for ultrasonic breast examinations

1.0 Submitter Information

1.1 This Premarket Notification is submitted by:

Delphinus Medical Technologies, Inc.
46701 commerce Center Drive
Plymouth, Michigan 48170

1.2 Contact Information:

Contact Name: Andrea N. Wallen-Gerding
Office Telephone: 734-233-3984
Fax: 734-207-3165
E-mail: awallen@delphinusmt.com

1.3 Date**:** September 5, 2014

2.0 Device Name

2.1 Trade/ Proprietary Name: SoftVue

2.2 Common Name:

- System, Imaging, Pulsed Echo Ultrasonic
- Transducer, Ultrasonic, Diagnostic

2.3 Classification Name:

- 21 CFR § 892.1560: Ultrasonic pulsed echo imaging system
- 21 CFR § 892-1570: Diagnostic ultrasonic transducer

3.0 Predicate Device

The predicate device is identified as SoftVue™ manufactured by Delphinus Medical Technologies. SoftVue™ received market clearance under 510(k) number K123209.

The Toshiba Aplio 500 (K133761) was used as a secondary predicate device for elastography image comparison.

4.0 Device Description

SoftVue™ is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast using a curvilinear array transducer that completely surrounds the breast. The modification of SoftVue™ will allow the system to generate colorized and grayscale relative stiffness ultrasound images in addition to the grayscale B-mode images generated by the unmodified SoftVue™ system. This new feature will allow the user to be able to determine

whether a region of interest is harder or softer than the surrounding tissue. No clinical diagnostic claims are being made.

SoftVue™ is comprised of the following subsystems: the Transducer, Table/Housing Assembly, Water Conditioning System, Computer Control System, Image Reconstruction System, Power System, and the Data Acquisition System.

SoftVue™ has a built-in curvilinear transducer that is used to acquire ultrasound data. Data are acquired from a patient lying prone on the table with their breast submerged in an imaging chamber filled with warm (body temperature) water. The breast is positioned in the center of the transducer. A camera, located at the bottom of the imaging chamber provides a live video feed to the system operator to aid in positioning the patient's breast. Once the scan is initiated, the transducer collects data that are processed to produce a series of B-mode ultrasound image slices that can be stacked to yield a volumetric ultrasound image of the breast. SoftVue™ also outputs colorized and grayscale relative stiffness image stacks that provide the radiologist with additional reference information.

The Water Control System is used to de-gas and warm the water that is used as the image acquisition medium. The Computer Control System controls all of the functionality of the other subsystems. The reconstruction engine processes the image data acquired by the transducer ring into B-mode ultrasound images.

The system includes a barcode reader and a touchscreen display (user interface). The touchscreen display allows the user to perform an imaging procedure. Patient information is entered into the system using either the QWERTY keyboard on the touchscreen display, using the barcode reader, or the user can import the patient information from a DICOM modality worklist on an externally networked RIS server. Device errors and warnings are displayed on the touchscreen display.

SoftVue™ outputs the images to an externally networked PACS server which allows the images to be stored until they are reviewed on a workstation.

5.0 Intended Use

SoftVue™ is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning curvilinear array transducer. The device is not intended to be used as a replacement for screening mammography.

6.0 Predicate Device Comparison

Delphinus Medical Technologies claims that the SoftVue device is substantially equivalent to the SoftVue system cleared by the FDA in K123209. Delphinus Medical Technologies claims substantial equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, physical and operational specifications as compared to the predicate device.

The SoftVue device and the predicate device utilize B-mode grayscale ultrasound images to achieve their intended use. Both the modified SoftVue device and the unmodified 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 modified SoftVue device and the unmodified SoftVue device have been identified and explained in the Comparison Table section provided in Section 10 of this submission. A brief summary of the similarities and differences between the modified SoftVue device and the unmodified SoftVue device is included below. The differences noted between the modified SoftVue device and the unmodified SoftVue device do not present any new issues related to safety and effectiveness.

Similarities:

- The modified and unmodified SoftVue devices use an automated transducer to acquire 2D images of a patient's breast.
- The modified and unmodified SoftVue devices use broadband transducers.
- The modified and unmodified SoftVue devices have a single operating frequency of 3 MHz.
- Both systems acquire and process B-mode grayscale images of a patient's breast.
- Both systems position the patient in a prone position lying on their examination table with the patient's 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 modified and unmodified SoftVue systems are listed in Table 1 below.

Table 1: Changes made to Modified SoftVue System

Item #	Modification	Reason for Change
1	Added mesh to the spillage chamber.	Prevent debris from entering/ getting trapped and degrading valves.
2	Added a second membrane module to degasser	Improve degassing efficiency and maintain the same flow rate of water.
3	Replaced transmit power supplies with medical grade power supplies	Conform to 60601-1:2005
4	Replaced in-line filter with medical grade version	Conform to 60601-1:2005
5	Added Ethernet opto-isolator	Conform to 60601-1:2005
6	Replaced vacuum pump circuit breaker with lower amp circuit breaker	Conform to 60601-1:2005
7	Added thermistor interface board	Better match reservoir and imaging chamber

Item #	Modification	Reason for Change
		temperature sensors to more practical values
8	Added cleaning tools	Simplify cleaning process
9	Parallelized user login and system initialization	Allows the user to view the status of the initialization process.
10	Added ability to query external RIS server	Allows user to upload patient information for an exam.
11	Updated GUI	Updated to accommodate other changes made such as allowing research users to select between running a research or clinical exam, RIS query, and initialization status.
12	Added acquisition PCBA temperature monitoring	Safety feature
13	Transferred full control of motors to control computer	Streamline system operation
14	Added ability to generate and output color and grayscale relative stiffness images	Additional reference information for radiologists
15	Improved image quality by updating pre-processing of attenuation image (not displayed) and updating sound speed image parameters.	Improve image quality. • Updates to the pre-processing of the attenuation image result in better gain correction and equivalent contrast for the B-mode image. • Updates to the sound speed image parameters results in better delay correction and equivalent contrast for the B-mode image.
16	Fixed a bug in firmware on the digital image processing board	Improve acquisition reliability
17	Updated the Master Clock and PCIe Interface (MCP) Board to make clock signals more reliable	Improve initialization reliability

7.0 Summary of Non-Clinical Testing

7.1 The function and performance of the modified SoftVue device has been evaluated through non-clinical design verification and validation testing. Testing includes system performance and simulated use tests. The results of the evaluation tests demonstrate that the modified SoftVue device successfully meets the requirements of its intended use.

7.2 Delphinus Medical Technologies conducted performance evaluations to verify that SoftVue's subsystems successfully meet predetermined specifications and product performance requirements. Results of the testing performed demonstrate that SoftVue's subsystems meet the system and performance requirements necessary for its intended use. A brief list of some of the testing performed is included below.

7.2.1 Software Unit and System Verification and Validation Testing – Software was tested at the unit and system level 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 were raised.

7.2.2 Sub-system Verification Testing – SoftVue subsystems that were modified from the original SoftVue system that received clearance to market underwent subsystem verification to ensure that they met their respective design requirements. All requirements were met and no new issues of safety or effectiveness were raised.

7.2.3 System Verification Testing – Since there were modifications made to the SoftVue system as a whole, system verification testing was conducted to ensure that the modified SoftVue system met the design requirements. All requirements were met and no new issues of safety or effectiveness were raised.

7.2.4 Human Factors/Usability Testing: Usability testing was conducted per the FDA Guidelines and ANSI/AAMI HE75:2009. All requirements were met and no new issues of safety or effectiveness were raised.

7.2.5 Design Validation Testing – Testing was conducted to ensure that the modified SoftVue device met the user needs and intended use requirements. All requirements were met and no new issues of safety or effectiveness were raised.

7.3 SoftVue has undergone acoustic output testing per IEC 60601-2-37:2007. Testing was conducted by Acertara Acoustic Laboratories, an independent testing laboratory, located in Longmont, Colorado. SoftVue meets all Track 1 acoustic output requirements. The results of acoustic output testing are listed in Table 2 below. A copy of the test report can be found in **Appendix 09-E** of Section 9 (Declaration of Conformity) of this submission.

Table 2: Global Maximum Acoustic Output Values

Feature	Track 1 Exposure Level	SoftVue Level	Pass/Fail
Max. Mechanical Index (MI)	1.9	0.431	Pass
Max. $I_{SPTA.3}$	94 mW/cm^2	15.1 mW/cm^2	Pass
Max. Soft Tissue Thermal Index (TIS)		0.0006	

7.4 In addition to the tests listed above, the modified SoftVue device has also undergone testing to the safety standards listed in Table 3 below.

Table 3: Safety Testing Performed on SoftVue

Standard # and Date	Standard Title
IEC 60601-1:2005; Corr. 1:2006; Corr. 2:2007	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
IEC 60601-1-2:2007	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Tests (Edition 2:2001 with Amendment 1:2004)
IEC 62304:2006	Medical device software – Software life cycle processes

Standard # and Date	Standard Title
IEC 60601-2-37:2007	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

8.0 Summary of Clinical Testing

8.1 No clinical testing is required to be performed using SoftVue; however, image characterization testing using clinical data has been completed per study parameters suggested by the FDA during the Submission Issue Q-Sub Meeting (Q130909) held on August 23, 2013. The parameters are listed below.

- 10 – 20 patients
- Range of breast densities from Fatty to Dense Breasts
- Small to Large Breasts
- Lesion sizes 5 mm to 15 mm or 20 mm

8.2 The study was conducted in order to demonstrate SoftVue's ability to provide qualitative tissue stiffness information with the color relative stiffness images. The in-vivo comparisons are not meant to guide a statistical study, but are solely intended to provide an illustrative example of in-vivo stiffness imaging using the modified SoftVue System.

8.3 As part of the evaluation, a phantom analysis was also included in the test protocol to establish a baseline for the clinical image evaluations. An anthropomorphic breast phantom was chosen for this initial analysis because its characteristics are predetermined such that the stiffness properties of the entire phantom and its inclusions are accurately known. The phantom contains stiff and soft inclusions of varying sizes. Each of the masses in the phantom have known stiffness characteristics that have been used to demonstrate that the color of the masses within the color stiffness images output by SoftVue correlate to the stiffness of the masses within the anthropomorphic breast phantom. The appearance of each mass was used to qualitatively characterize the mass stiffness based on relative color differences.

8.3.1 The phantom scan yielded images of 7 inclusions. Among the 7 phantom inclusions, 1 cancer and 3 fibroadenomas were found to be stiff (appearing red) compared to the background material while the 3 cysts were found to be soft (appearing blue) in complete concordance with the known properties of the phantom.

8.4 Delphinus Medical Technologies conducted a small scale clinical study to collect clinical images from the modified SoftVue system. The images collected include B-mode images as well as color and grayscale relative stiffness images. Patient data were collected as part of the clinical study that Delphinus currently has in process under pre-IED # I120143. A modified SoftVue system has been installed at the Alexander J Walt Breast Center at the Karmanos Cancer Institute located in Detroit, Michigan.

8.5 The image evaluations were conducted per protocol 100-00745, *SoftVue Color Stiffness Image Characterization Protocol* (**Appendix 20-A**).

8.6 The patient data were chosen from the clinical study on the basis of having a suspicion or a biopsy proven lesion such that the lesions in question could be identified by:

8.6.1 Appearance (echogenicity)

8.6.2 Size (dimensions)

8.6.3 Location (clock position)

8.7 All patient images from the SoftVue system were reviewed by board certified radiologist, Dr. Peter Littrup. Previous biopsies and/or imaging were used to guide the identification of the lesions in the SoftVue images using clock position, appearance, size and location for guidance.

8.8 A set of 10 representative in-vivo comparisons of SoftVue's B-mode and color relative stiffness images was carried out to demonstrate SoftVue's ability to qualitatively measure tissue stiffness with clinical data, using the B-mode images for initial mass identification.

8.8.1 A total of 10 SoftVue patient exams were used in the analysis. Some patients had multiple lesions so that the final data set consisted of 13 imaged masses consisting of 4 cancers, 4 fibroadenomas, and 5 cysts.

8.8.2 Breast cup size ranged from B to DDD with densities consisting of 5 scattered, 2 heterogeneous and 3 dense (one of which was extremely dense) indicating that a range of breast size and density was sampled.

8.9 All 4 cancers were characterized as "stiff" by SoftVue's color stiffness images. Two fibroadenomas were found to be mixed (range of colors), 1 was stiff (red) and 1 was found to be soft (blue). Of the 5 cysts, 4 were found to be soft, while 1 was found to be mixed. A summary of the results are included in Table 4 below.

Table 4: Clinical Image Analysis Summary

Mass #	Case #	Study #	Breast Size	Breast Density	Lesion Pathology	Reported Lesion Position	Average Lesion Size (cm)	SoftVue Appearance	SoftVue Stiffness Assessment
1	**1**	**SV021**	C	Dense	Cancer	8:00	2.5	Hypoechoic Red / green (redder than background on average)	Stiff
2	**2**	**SV022**	DD	Scattered	Fibroadenoma	1:30	3.0	Hypoechoic Yellow / green (redder than background on average)	Stiff
3	**3**	**SV045**	C	Scattered	Cancer	10:00	1.8	Hypoechoic Red (redder than background on average)	Stiff
4	**4**	**SV077_1**	B	Extremely Dense	Cyst	2:00	1.4	Anechoic Blue/green (bluer than background on average)	Soft
5	**4**	**SV077_2**	B	Extremely Dense	Cyst	12:00	1.9	Anechoic Blue/green (bluer than background on average)	Soft

Mass #	Case #	Study #	Breast Size	Breast Density	Lesion Pathology	Reported Lesion Position	Average Lesion Size (cm)	SoftVue Appearance	SoftVue Stiffness Assessment
6	**4**	**SV077_3**	B	Extremely Dense	Cyst	12:00	2.0	Anechoic Blue/green (bluer than background on average)	Soft
7	**5**	**SV079**	C	Heterogeneous	Cyst	9:00	1.4	Anechoic Blue/green (bluer than background on average)	Soft
8	**6**	**SV089**	D	Scattered	Cancer	9:30	1.7	Hypoechoic Red (redder than background on average)	Stiff
9	**7**	**SV090**	DDD	26yrs (Hetero)*	Fibroadenoma	10:00	4.3	Hypoechoic Blue/Green (range of color, no dominant color)	Mixed
10	**8**	**SV113**	DD	Scattered	Cyst	2:00	1.8	Anechoic Blue/green (range of color, no dominant color)	Mixed
11	**9**	**SV114**	D	Scattered	Cancer	10:00 RA	1.2	Hypoechoic Red/green (redder than background on average)	Stiff
12	**10**	**SV117_1**	D	21yrs (Dense)*	Fibroadenoma	5:00	1.9	Hypoechoic Blue/green/red (range of color, no dominant color)	Mixed
13	**10**	**SV117_2**	D	21yrs (Dense)*	Fibroadenoma	8:00	2.6	Hypoechoic Blue (range of color, no dominant color)	Soft

9.0 Conclusion

The modified SoftVue device performs as intended and is substantially equivalent to the unmodified SoftVue device with respect to intended use, design, principles of operation, technology, materials, and performance. Any noted differences do not raise any new issues of safety and effectiveness.