DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2017

ADECHO TECH
C/O THOMAS KNOTT
SENIOR REGULATORY ADVISOR
810 LANDMARK DRIVE
SUITE 126
GLEN BURNIE MD 21061

Re: K161354
Trade/Device Name: Melody, Remote Control System for Ultrasound Probe
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX, IYN
Dated: May 8, 2017
Received: May 10, 2017

Dear Mr. Knott:

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)*
K161354

Device Name
Melody, Remote Control System for Ultrasound Probe

Indications for Use *(Describe)*
The MELODY is intended to hold the external ultrasound transducer of cleared ultrasound equipment and provide a remotely-located, expert sonographer the ability to manipulate the transducer in real time through an Internet connection to obtain the ultrasound views required to assess the patient. The MELODY robot frame at the remotely-located patient is prepared and positioned by a trained assistant at the direction of the expert sonographer through a suitable third-party videoconferencing system. Sonograms are transmitted from the patient location from cleared ultrasound equipment through digital telecommunication to the expert sonographer. Indications for the MELODY are tabulated in the Diagnostic Ultrasound Indications table. MELODY may also be used when a physician wants to have a colleague not on-site provide a second opinion.

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.

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

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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	N	N	N	N	N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Specify)	N	N	N	N	N	N	N
	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	N	N	N	N	N	N	N
	Other (Specify)							
	Pelvic	N	N	N	N	N	N	N
	Urology	N	N	N	N	N	N	N

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

510(k) Summary (21 CFR 807.92)

I. SUBMITTER

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II. DEVICE

Proprietary Name:	MELODY, Remote Control System for Ultrasound Probe
Common Name:	Robotic tele-sonography device
Classification:	Accessory to: 1. Ultrasonic pulsed echo imaging system 2. Transducer, Ultrasonic, Diagnostic 3. System, Imaging, Pulsed Doppler, Ultrasonic
Classification Regulation:	1. 21 CFR 892.1560; 2. 21 CFR 892.1570; 3. 21 CFR 892.1550
Product Code:	1. IYO, 2. ITX, 3. IYN
Review Panel:	Radiology
FDA Document Numbers Related To Melody	Q150951
Predicate Device(s):	K082543, SonoCiné Adjunctive Breast Ultrasound System (ABU), Model 100

III. PREDICATE DEVICE

K082543; SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100 cleared under (System, Imaging, Pulsed Echo, Ultrasonic; product code: IYO).

This predicate has not been subject to a design-related recall.[1]

IV. DEVICE DESCRIPTION

The objective of the MELODY, Remote Control System for Ultrasound Probe, is to allow an expert sonographer to manipulate the transducer of a third-party ultrasonic device remotely and in real time over an internet or similar connection. The remote expert manipulates the precession, nutation, and intrinsic rotation of the transducer, replicating the motions of the hand, to obtain the exact sonography views that he or she requires. The MELODY solves the problem of a lack of imaging experts in isolated areas, e.g., small or rural hospitals or clinics, remote military medical facilities, ships or oil drilling platforms, prison environment, etc.

V. INDICATIONS FOR USE

The MELODY is intended to hold the external ultrasound transducer of cleared ultrasound equipment and provide a remotely-located, expert sonographer the ability to manipulate the transducer in real time through an Internet connection to obtain the ultrasound views required to assess the patient. The MELODY robot frame at the remotely-located patient is prepared and positioned by a trained assistant at the direction of the expert sonographer through a suitable third-party videoconferencing system. Sonograms are transmitted from the patient location from cleared ultrasound equipment through digital telecommunication to the expert sonographer. Indications for the MELODY are tabulated in the Diagnostic Ultrasound Indications table. MELODY may also be used when a physician wants to have a colleague not on-site provide a second opinion.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

MELODY is substantially equivalent to SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100. The technological characteristics are equivalent. MELODY and SonoCiné both secure the transducer for most FDA-cleared ultrasound systems. The transducer is secured to a robotic support mechanism that moves by signals from computer-driven servo motors. When MELODY or SonoCiné are not in use, the ultrasound system can be used for any other indicated ultrasound scans.

In both devices an assistant technologist positions and prepares the patient and the MELODY or SonoCiné robotic mechanism. In both, the assistant minimally guides or prepositions the robotics that is holding transducer. The technologist maintains the angle and contact pressure of the SonoCiné transducer. The technologist positions and steadies the MELODY frame on the patient at the direction of the distant sonographer.

The SonoCiné robotic arm movement is computer controlled by the SonoCiné software. SonoCiné is programmed to move in parallel and contiguous rows across the patient's breast and surrounding areas. SonoCiné Image Acquisition Station Model 100 records and stores the ultrasound images for viewing by

[1] On July 9, 2012, section 605 of FDASIA (Pub. L. 112-144) added section 518A to the FD&C Act, which directs FDA to establish a program to routinely and systematically assess information regarding device recalls, and to use that information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. FDA believes that one way to carry out this directive is to provide greater transparency on recalled devices. Identifying whether a predicate was recalled is optional, but doing so would help the Agency achieve this FDASIA directive.

the radiologist at a later time. The MELODY robotic tilts and rotates at the distant sonographer's command in real time. The software in the ultrasound device transmits the image to the radiologist in real time over the Internet connection. In neither device does the sonographer directly perform the scan in the presence of the patient.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the MELODY device was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the MELODY device, consisting of the patient and expert modules. The system complies with the IEC 60601-1, standard for safety, and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern because ultrasound device software is considered to be a moderate level of concern and because a failure or latent flaw in the software could directly result in minor injury to the patient or operator. The level of concern is also moderate if a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Mechanical Performance Validation

The MELODY expert system was tested to validate the performance of position orders generated and the MELODY patient system was tested to validate the performance for applying the position orders from the expert system. The testing demonstrated that the MELODY performed within predetermined specifications for all three rotational motions for positioning the MELODY robot. Additionally, the maximal delay for orders processing met the predetermined specification.

Clinical Studies

The MELODY was tested in several clinical studies reported in the scientific literature. Separate examinations were performed on over 500 patients of abdominal, pelvic, fetal, cardiac, or vascular organs. Results from distance sonograms were compared to sonograms done on location at the patient's side by a second expert sonographer and during resulting examinations and procedures. Patients with pathologic conditions and those that were normal were scanned. Organs were both visualized and measured.

Primary effectiveness endpoint:
The distance sonogram yielded the same visualization, diagnosis, and/or measurement as a sonogram performed at the patient's side.

Effectiveness
Visualization scores ranged from 81% to 100% versus the on-site sonograms. Measurements were not found to differ statistically significantly from on-site measurements. In a few instances, self-imposed time limits did not provide the time to complete measurements. Compression and decompression of the internet signal affected the contrast and resolution of the images. Consequently some small lesions were not observable and low contrast images were harder to diagnose. Patients that presented sonography difficulties, e.g., obesity, were harder to diagnose at a distance.

Safety
No adverse effects were experienced from the MELODY itself. It is designed to apply no more than 20 N of pressure to the skin surface. The weight MELODY frame itself is supported by a floor mounted stand.

Summary
Based on the clinical performance as documented in the reported clinical studies, the MELODY system was found to be safe and effective.

VIII. CONCLUSIONS

MELODY is substantially equivalent to the predicate device. The technological characteristics of MELODY and the predicate devices are essentially equivalent. The robotic control differs, but both are designed to obtain sonograms through third party ultrasound devices. The indication for the sonograms differs. While both obtain sonograms, the predicate is indicated for the breast only, but MELODY is indicated for pelvic, abdominal, cardiac, and vascular organs, but not the breast.

--- END OF 510(k) SUMMARY ---