March 12, 2019

Sonavex, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K190039
Trade/Device Name: EchoSure Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX, IYN
Dated: February 25, 2019
Received: February 26, 2019

Dear Mr. Job:

This letter corrects our substantially equivalent letter of March 8, 2019.

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.

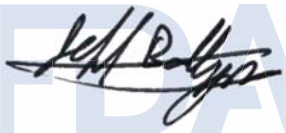
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Thalia Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
EchoSure Diagnostic Ultrasound System

Indications for Use *(Describe)*
The EchoSure diagnostic ultrasound system and its transducer are intended for use in clinical examinations of blood vessels that are marked with an EchoMark or EchoMark LP implant. The system provides measurements and information about blood flow.

The system is intended for use by trained medical health care professionals in support of clinical diagnosis.

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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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Table

System: EchoSure Diagnostic Ultrasound System
Transducer: EchoSure Probe 4DML12-5

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 (Specify)							
	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(B+Color)	
	Other (Specify)							

N = new indication;

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared: November 18, 2018

Applicant:
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Trade Name: EchoSure

Common Name: Diagnostic Ultrasound System

Classification Names: Ultrasound Pulsed Echo Imaging System, 21 CFR 892 1560, Product Code IYO

Diagnostic Ultrasound Transducer, 21 CFR 892.1570, Product Code ITX

Ultrasound Pulsed Doppler Imaging System, 21 CFR 892.1550, Product Code IYN

Device Classification: Class II

Product Codes: IYO, ITX, IYN

Predicate Device: K173265, WinProbe UltraVision 2 Diagnostic Ultrasound System

Substantially Equivalent to:
EchoSure is substantially equivalent in intended use, principle of operation and technological characteristics to the UltraVision 2 Diagnostic Ultrasound System cleared under premarket notification K173265.

Description of the Device Subject to Premarket Notification:
EchoSure is a portable diagnostic ultrasound system which applies the latest technologies to produce optimal images and provide information about blood flow in vessels. Various image parameter adjustments, dual high-resolution displays, and a custom probe are configured to provide clear and stable images. The system operates in B-Mode and Color Flow Doppler Mode. EchoSure is comprised of the EchoSure Ultrasound, the EchoSure Application, and the EchoSure Probe.

Indications for Use:
The EchoSure diagnostic ultrasound system and its transducer are intended for use in clinical examinations of blood vessels that are marked with an EchoMark or EchoMark LP implant. The system provides measurements and information about blood flow.

The system is intended for use by trained medical health care professionals in support of clinical diagnosis.

Technical Characteristics Compared to Predicate Device:
EchoSure uses the same fundamental scientific technologies as the predicate device (K173265, WinProbe UltraVision 2 Diagnostic Ultrasound System). Table 1 compares EchoSure to the predicate device with respect to indications for use, and principles of operation for the determination of substantial equivalence.

Table 1. Predicate Device Comparison

	EchoSure	UltraVision 2 Diagnostic Ultrasound System (K173265)
Description	EchoSure is a portable diagnostic ultrasound system that enables a clinician to evaluate blood flow in vessels. EchoSure functions well within the operational performance specifications of the UltraVision 2.0 platform for B-mode and Color Flow Doppler-mode operations.	The UltraVision is a portable Diagnostic Ultrasound System, which applies the latest technologies to produce optimal images. The system facilitates a workflow from image acquisition through to archival in a standard DICOM interface to the clinics PACS system. Various image parameter adjustments, dual, high-resolution displays and custom probes are

		configured to provide clear and stable images. It operates in B, M, Color Flow Doppler, Shear Mode, PW Doppler Mode, and E Mode. The various uses of UltraVision 2.0 include evaluation of blood vessels, as seen in EchoSure.
Indications for Use	The EchoSure diagnostic ultrasound system and its transducers are intended for use in clinical examinations of vessels. The system provides measurements and information about blood flow. The system is intended for use by trained medical health care professionals in support of clinical diagnosis.	This diagnostic ultrasound system and its transducers are indented for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients, (thyroid, breast, and testicles) and for peripheral vessel, abdominal and superficial muscular skeletal diagnosis.
Power Supply		
Voltage	100 – 264 V AC (power supply label)	90-264 V AC (as listed in submission)
Frequency	47-63 Hz (power supply label)	50/60 Hz (as listed in submission)
Operational Characteristics		
Installation and use	Portable equipment. Mobile when installed in mobile cart	Portable equipment. Mobile when installed in mobile cart
Mode of operation	Continuous operation	Continuous operation
Physical Specifications		
Dimensions	400 mm (W) x 55 mm (H) x 250 mm (D)	400 mm (W) x 50 mm (H) x 250 mm (D)
Weight	5.9 kg (~13lbs)	4.5 kg (~10lbs)
Temperature		
Operating	0°C to 40°C	0°C to 40°C
Transport/ Storage	Equipment should not be subject to excessive temperatures during transportation/storage	Equipment should not be subject to excessive temperatures during transportation/storage
Relative Humidity		

Operating	0% - 90% relative humidity	Equipment should not be used in locations of high humidity
Transport/Storage	0% - 90% relative humidity	Equipment should not be used in locations of high humidity
Safety Classifications		
Type of protection against electric shock	Class II	Class II
Degree of protection against electric shock	Type BF	Type BF
Degree of safety of application in the presence of a flammable gas	Equipment not to be used in the presence of a flammable gas	Equipment not to be used in the presence of a flammable gas
Compliance with electrical, mechanical and safety standards	Complies with the standard: ES60601-1 / IEC 60601-1 IEC 60601-2-37	Complies with the standard: IEC 60601-1 IEC 60601-2-37
EMC Compliance with standards	Complies with the standard: IEC 60601-1-2	Complies with the standard: IEC 60601-1-2
Acoustic output evaluation	Complies with the standard: IEC 61157 AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound	Complies with the standard: IEC 61157 AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
Biocompatibility Evaluation	Complies with the standard: ISO 10993-1	Complies with the standard: ISO 10993-1
Disinfection	Probe: .55% Ortho Phthalaldehyde, 2.4% Glutaraldehyde	Probe: .55% Ortho Phthalaldehyde, 2.4% Glutaraldehyde
Specifications		
Monitor	15.6 inch IGZO 3200 x 1800 pixel image display Refresh Rate: 60 Hz Aspect Ratio: 16x9	15 inch display LCD flat panel display with 2800 x 1800 pixels
General Imaging Mode	B mode, Color Flow Doppler mode	B mode, M mode, E mode, Color Flow Doppler mode, Shear mode

Scanning Method	Linear	Linear
Focus number	Max = 4	Max = 4
Peripheral Devices supported		
Rolling Cart	EchoSure Roll Stand	TBD
Performance		
Displayed depth	10 mm – 80 mm	20 mm to 300 mm
Gray scales	256	256
TGC	8 segments	8 segments
Image Adjustments		
B mode parameters	Gain, Depth, TGC, Frequency	Gain, Depth, TGC, Frequency
Color Flow Doppler Mode	Transmit Frequency, Gain, Pulsed repetition frequency	Transmit Frequency, Gain, Persistence, Pulsed repetition frequency, Smoothing, Map

Intended Use Comparison:
The intended use and clinical applications for EchoSure are the same or limited compared to the predicate device. Both systems are intended to be used with a conventional extracorporeal transducer. The EchoSure Probe is a 4D linear transducer specified for use with EchoSure. Comparison of the transducers is provided in Table 2:

Table 2. Probe Comparison

	EchoSure Probe 4DML12-5	Predicate Probe L14-4
Type	Linear	Linear
Frequency Bandwidth	5 – 12 MHz	5 - 15 MHz
Applications	• Vascular	• Breast • Testes • Thyroid • Musculoskeletal • Peripheral Vessel • Abdominal
Number of elements	192	256
Modes of operation	B and CFD	B, E, M, CFD, PWD
Array footprint	55 mm	52 mm

Acoustic output display standard	Track 1	Track 1
Mechanical Index (MI)	0.8	0.82
I_{SPTA} (mW/cm^2)	106	75
P_r (MPa)	2.75	2.142
Frequency (MHz)	6.85	7.55

Non-clinical Safety and Performance Data:
All necessary testing has been performed for EchoSure to assure substantial equivalence to the predicate device and to demonstrate that the device performs as intended.

The following ISO 10993 biocompatibility and safety testing was performed on the EchoSure Probe. Results from the tests indicate that the device is non-toxic, non-sensitizing, non-mutagenic and non-irritating therefore biocompatible for its intended use:

- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

Performance and safety testing, Bench: Successful completion of the following tests confirmed that risk controls were properly implemented, and design outputs meet design inputs and device is suitable for its intended use:

- AAMI/ANSI ES 60601-1:2005/(R)2012 And A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Capability – 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.

- Acoustic output testing per the FDA Guidance “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound and Transducers” dated September 9, 2008, and Draft Guidance dated 2017, including IEC 61157 testing as required.

Conclusion:
Clinical studies are not required to support equivalence for these conventional ultrasound systems. EchoSure is in conformance with the standards described above which are the same or equivalent to those performed on the predicate UltraVision 2 system. EchoSure met all specified criteria and did not raise new safety or performance questions and therefore support a finding of substantial equivalence.

Basis for Determination of Substantial Equivalence:
The Indication/Intended Use, the fundamental scientific technology, and differences between EchoSure and the predicate device do not raise new questions of safety and/or effectiveness. EchoSure has been determined to be substantially equivalent to the predicate device.