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

Echosens
% Zvi Ladin, Ph.D.
Principal
Boston MedTech Advisors, Inc.
990 Washington Street, Suite #204
DEDHAM MA 02026

June 3, 2015

Re: K150949
Trade/Device Name: Fibroscan®
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: March 31, 2015
Received: April 8, 2015

Dear Dr. Ladin:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*

K150949

Device Name
FibroScan®

Indications for Use *(Describe)*

The FibroScan® system is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body.

FibroScan® is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The shear wave speed and stiffness, and CAP may be used as an aid to clinical management of adult patients with liver disease.

Shear wave speed and stiffness may be used as an aid to clinical management of pediatric patients with liver disease.

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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"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 Intended Use

System: FibroScan® 502 Touch

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		P					P 1, 2 N 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric		P					P 1, 2
	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							
	Other (Specify)							

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

1. A-mode
2. Vibration Controlled Transient Elastography at 50 Hz
3. Controlled Attenuation Parameter at 3.5 MHz

Diagnostic Ultrasound Intended Use

Transducer: FibroScan® M+ probe

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		P					P 1, 2 N 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric		P					P 1, 2
	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							
	Other (Specify)							

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

1. A-mode
2. Vibration Controlled Transient Elastography at 50 Hz
3. Controlled Attenuation Parameter at 3.5 MHz

Diagnostic Ultrasound Intended Use

Transducer: FibroScan® XL+ probe

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		P					P 1, 2 N 3
	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							
	Other (Specify)							

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

1. A-mode
2. Vibration Controlled Transient Elastography at 50 Hz
3. Controlled Attenuation Parameter at 3.5 MHz

Diagnostic Ultrasound Intended Use

Transducer: FibroScan® S+ probe

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		P					P 1, 2
	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							
	Other (Specify)							

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

1. A-mode
2. Vibration Controlled Transient Elastography at 50 Hz

510(K) Summary
Echosens' FibroScan® System

Submitter's Name, Address, Telephone Number, Contact Persona and Date Prepared:

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Date Prepared: June 1, 2015

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan®

Common Name: Diagnostic Ultrasound System and Accessories

Classifications:

Classification Name	Regulation	Product Code
Ultrasonic Pulsed Echo Imaging System	21 CFR §892.1560	IYO
Diagnostic Ultrasonic Transducer	21 CFR §892.1570	ITX

Manufacturing Facility: Echosens
30 Place d'Italie
75013 Paris, France
Telephone: +33 1 44 82 78 55
Facsimile: +33 1 44 82 68 36

Establishment
Registration Number: 3010258456

Predicate Device
This submission claims substantial equivalence to a combination of three cleared devices:

Primary Predicate:

- FibroScan® (#K123806) manufactured by the sponsor and cleared on April 5, 2013; and

Secondary Predicate:

- SoftVue® (#K142517) manufactured by Dephinus Medical Technologies, Inc. and cleared on October 31, 2014

Device Description

FibroScan®, based on Vibration-Controlled Transient Elastography (VCTE™) technology, is designed to perform non-invasive measurements of liver shear wave speed and estimates of tissue stiffness. A mechanical vibrator produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver. The speed of propagation of the shear (elastic) wave is measured using ultrasounds. A new FibroScan® parameter labeled CAP (Controlled Attenuation Parameter), ranging between 100 and 400 decibels per meter (dB/m), provides an estimation of the total aforementioned ultrasonic wave attenuation (forward and return paths) at 3.5 MHz, measured concomitantly with tissue stiffness.

Intended Use / Indications for Use

The FibroScan® system is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body.

FibroScan® is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The shear wave speed and stiffness, and CAP may be used as an aid to clinical management of adult patients with liver disease.

Shear wave speed and stiffness may be used as an aid to clinical management of pediatric patients with liver disease.

Comparison of Technological Characteristics[1]

Controlled Attenuation Parameter (CAP) is designed to estimate the ultrasound attenuation (forward and return paths) at the frequency of 3.5 MHz, using the M+ and XL+ transducers. The candidate FibroScan system with the additional CAP calculations (ranging from 100 to 400 dB/m) and display feature is otherwise identical to the predicate FibroScan systems (FibroScan® – #K123806, manufactured by the sponsor), as related to the transducers used, examination procedure, technical characteristics, imaging capabilities, information processing, and performance measurements.

The soft tissue attenuation application of the candidate FibroScan system is substantially equivalent to the attenuation applications in the secondary predicate SoftVue® – #K142517.

The SoftVue system displays a colored ultrasonic image that depicts a quantitative descriptions of soft tissue in three modes: reflection, sound speed and attenuation. Operating at a similar central frequency as the candidate device, attenuation images are reconstructed based on

[1] Guidelines indicate that if the Indications for Use are different from those of the predicate device, a brief explanation is required to address why the differences in the Indications do not affect the safety and effectiveness of the device and do not alter the intended therapeutic, diagnostic, prosthetic, or surgical use of the device.

acoustic wave amplitude changes. Additionally, the attenuation image measure by SoftVue is displayed only if the sound speed measurement exceeds a defined threshold. Though both devices use attenuation measurements, the SoftVue attenuation information is displayed differently than the candidate FibroScan device as the attenuation measurements are not provided separately but rather fused together with the sound speed and reflection images.

Consensus Standards Used

Non-clinical testing to assure compliance with acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety were performed and have been found to conform to applicable medical device safety standards. The system complies with the following standards:

- IEC 60601-2-37 Edition 2.0 2007-08: 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
- AIUM MUS: Medical Ultrasound Safety, Third Edition
- IEC 62127-1 Edition 1.1 2013-02: Ultrasonics -- Hydrophones -- Part 1: Measurement And Characterization Of Medical Ultrasonic Fields Up To 40 Mhz
- IEC 62127-2 Edition 1.0 2007-08: Ultrasonics -- Hydrophones -- Part 2: Calibration For Ultrasonic Fields Up To 40 Mhz [Including: Technical Corrigendum 1:2008 And Amendment 1:2013]
- IEC 62127-03 Edition 1.1 2013-05: Ultrasonics -- Hydrophones -- Part 3: Properties Of Hydrophones For Ultrasonic Fields Up To 40 Mhz
- IEC 61161 Edition 3.0 2013-01: Ultrasonics -- Power Measurement -- Radiation Force Balances And Performance Requirements
- AAMI / ANSI ES60601-1:2005/(R)2012: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod)
- 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 Compatibility - Requirements And Tests
- IEC 60601-1-6 Edition 3.1 2013-10: Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 62366 Edition 1.1 2014-01: Medical Devices - Application Of Usability Engineering To Medical Devices
- IEC 62304 First Edition 2006-05: Medical Device Software - Software Life Cycle Processes
- ISO 14971 Second Edition 2007-03-01: Medical Devices - Application Of Risk Management To Medical Devices

Performance Data

The accuracy and precision of the device was documented based on tests performed on phantoms with known attenuations. The bias, i.e. the difference in the mean CAP measured and the nominal CAP of the phantom, normalized by the nominal CAP and expressed as a percentage, was evaluated and compared to the corresponding value reported for the predicate devices.

While the FibroScan® predicate device reported minimum and maximum shear wave bias values of [-11.5%; 0.7%] for the M+ probe and [-13.9%; 1.3%] for the XL+ probe; the range of CAP bias values measured for the candidate device were between [-4.9%; -0.4%] for the M+ probe and [-3.5%; 6.5%] for the XL+ probe. Therefore, the overall range of bias values for the FibroScan predicate device probes are <13% and <16% for the M+ and XL+ probes respectively, while the corresponding values for the CAP bias in the candidate device is <5% and 10% respectively.

Similarly, the system's precision, i.e. the standard deviation of the independent measurements of the CAP, normalized by the reference value was calculated. The range of values reported for the Fibroscan® predicate device shear wave precision measurements is between [0.6%; 1.9%] for the M+ probe and [0%; 3.1%] for the XL+ probe, while the CAP measurement precision range for the candidate device is between [0%; 0.1%] for the M+ probe and [0.4%; 1%] for the XL+ probe. Therefore, the range of precision for the predicate device is <2% and <4% for the M+ and XL+ probes respectively, while for the candidate device it is <1% for both probes.

In summary, the FibroScan candidate device has bias and precision values that are similar or better than that of the predicate FibroScan device. Therefore, based on the bench testing documented in the submitted study reports, the FibroScan system was found to have a safety and effectiveness profile that is similar to its predicate devices.

Substantial Equivalence

The FibroScan® system and transducers, by Echosens, are similar to the predicate devices with regard to intended use, technology, and imaging capabilities. In addition, based on bench testing conducted with the FibroScan system ensures that the CAP meets specifications and should perform as intended in the specified use conditions. The accuracy and precision of the device were found to be substantially equivalent to those of the predicate device. Therefore, the device raises no new issues of safety or effectiveness.