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

September 1, 2015

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

Re: K150239
Trade/Device Name: FibroScan
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: July 30, 2015
Received: August 3, 2015

Dear Zvi 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.
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)*
K150239

Device Name

FibroScan®

Indications for Use *(Describe)*

The FibroScan® system is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness through internal structures of the body.

FibroScan® is indicated for noninvasive measurement of shear wave speed and estimate of stiffness at 50 Hz in the liver. The shear wave speed may be used as an aid to clinical management of pediatric and adult 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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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
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric		N					N 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

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
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric		N					N 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

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
	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

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		N					N 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:

Manufacturer:
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Contact Person:
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Date Prepared: July 30, 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 two cleared devices:
1. FibroScan® (#K123806) manufactured by the sponsor and cleared on April 5, 2013; and
2. Aixplorer® (#K132274) manufactured by Supersonic Imagine S.A. and cleared on September 24, 2013.

Device Description

FibroScan® system consists of a system unit and a hand-held probe. It is based on Vibration-Controlled Transient Elastography (VCTE™) technology, and is designed to perform non-invasive measurements of liver shear wave speed and estimates of tissue stiffness. The probe containing a mechanical vibrator produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver. Ultrasound is used to track the shear (elastic) wave, measure its speed and provide estimated stiffness. The results are displayed on the system unit.

The focus of this submission is the expansion of the indications for use for the FibroScan system by Echosens to pediatric patients. In order to address the smaller anatomic size of pediatric patients, a new probe (S+) was developed, and the indications for use of the previously cleared M+ probe were modified. The new probe uses the same principle of operation, intended use and methodology (i.e. application to patient, signal measurement, processing and display), design, materials, manufacturing and testing processes as the previously cleared M+ and XL+ probes. The device specifications are similar to those of the predicate device. The system's software was upgraded to accommodate these changes.

Recognized Consensus Standards Used

Non-clinical testing to assure compliance with acoustic output, biocompatibility as well as thermal, electrical, electromagnetic and mechanical safety were performed and have been found to conform to applicable 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 bias and precision of the device was documented based on tests performed on phantoms with known elasticity. The bias, i.e. the difference in the mean shear wave speed measured and the nominal shear wave of the phantom, normalized by the nominal shear wave and expressed in percent was evaluated and compared to the corresponding value reported for the predicate devices. While the Aixplorer® predicate device[1] pediatric probes reported values of bias between (-7.2%) and (43.4%), and the FibroScan® predicate devices reported values of bias between (-13.9%) and (1.3%); the range of bias values measured for the candidate device were between (-13.5%) and (3.6%). Therefore, the overall range of bias values (across all values) for the Aixplorer predicate device probes are ~50% of the nominal shear wave speed, while the corresponding range for the predicate FibroScan probes and for the candidate device probe is <20%. Hence, the candidate device has a bias value that is similar or better than that of the predicate device.

Similarly, the system's precision, i.e. the standard deviation of the independent measurements of the shear wave speed, normalized by the reference value was calculated. The range of values reported for the Aixplorer® predicate device pediatric probes were between (0%) and (3.4%), and for the FibroScan® predicate device probes were between (0%) and (3.1%), while the corresponding range for the candidate device probe was between (0.7%) and (2%). Therefore, the precision of all systems is similar – range of precision values of ~3% for the predicate device and ~2% for the candidate device.

Intended Use / Indications for Use

FibroScan® is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness through internal structures of the body.

FibroScan® is indicated for noninvasive measurement of shear wave speed and estimate of stiffness at 50 Hz in the liver. The shear wave speed may be used as an aid to clinical management of pediatric and adult patients with liver disease.

Comparison of Technological Characteristics

[1] The specific values of precision and bias for the AIXPLORER system are quoted from the 510(k) Summary of #K112255 which is the predicate for #K132274 and is stated to have a substantially equivalent non-clinical performance

The new S+ probe and the revised software are substantially equivalent to the predicate device (FibroScan® – #K123806) manufactured by the sponsor and cleared on April 5, 2013. The proposed device uses the same technology, intended use and methodology (i.e. application to patient, signal measurement, processing and display) as the FibroScan system. It is designed to accommodate the anatomy of pediatric patients.

The expansion of the Indications for Use of the FibroScan System with the new S^+ probe to include pediatric patients is substantially equivalent to the diagnostic ultrasound Indications for Use of the ShearWave™ Elastography mode of the Aixplorer (#K132274) for pediatric patients. The candidate device uses the S^+ ultrasound transducer at a center frequency of 5 MHz, which is in the range of frequencies used by the Aixplorer predicate system for pediatric applications. The analog front end and central control interface of the candidate and predicate devices have equivalent functionality.

In summary, the candidate and predicate devices are based on the same physical phenomenon, namely the effect of soft tissue elasticity on the propagation of low frequency mechanical waves in internal organs. They use ultrasound for measuring the changes in the strain field that results from the propagation of the mechanical wave, and display the shear wave speed and stiffness estimate. Therefore, the candidate and predicate devices are substantially equivalent in terms of the technology used.

Substantial Equivalence Discussion

The focus of this submission is the expansion of the indications for use for the FibroScan system by Echosens to pediatric patients. Therefore, substantial equivalence is claimed to the primary predicate device – the original FibroScan System (#K123806) in terms of the intended use, scientific principle, technological design, materials used, patient interface, data collection, processing and display. Substantial equivalence is also claimed to the secondary predicate device (AIXPLORER® #K132274), in terms of the indications for use (elastography for pediatric population), technological characteristics, signal acquisition, processing and display.

In order to address the smaller anatomic size of pediatric patients, a new probe (S+) was developed, and the indications for use of the M+ probe were modified. The center frequency of the S+ probe is well within the range of frequencies used by the predicate device (Aixplorer) for pediatric patients. The system's software was upgraded to accommodate these changes. The new probe uses the same principle of operation, design, materials, manufacturing and testing processes as the primary predicate. Therefore, the new S+ probe does not raise different questions of safety and effectiveness compared to the predicate devices.

Bench testing was performed to assure that the device meets its specifications. Measurements of the bias and precision of the device demonstrated substantial equivalence to both predicate devices.

A summary of the comparison between the candidate and predicate devices leading to the conclusion that the candidate device raises no new issues of safety or effectiveness is presented in the following table:

	FibroScan® – Pediatric Use	FibroScan®	Aixplorer®
510(k) #	K150239	K123806	K132274
Indications for Use	FibroScan® is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness through internal structures of the body. FibroScan® is indicated for noninvasive measurement of shear wave speed and estimate of stiffness at 50 Hz in the liver. The shear wave speed may be used as an aid to clinical management of pediatric and adult patients with liver disease. Prescription Use Device	FibroScan® is intended to provide 50Hz shear wave speed measurements through internal structures of the body. FibroScan® is indicated for noninvasive measurement of shear wave speed at 50 Hz in the liver. The shear wave speed may be used as an aid to clinical management of patients with liver disease. Prescription Use Device	The SuperSonic Imagine AIXPLORER®) ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal. The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Transrectal and Trans-vaginal).
Clinical Application	Pediatric	Abdominal	Abdominal Pediatric Other
Ultrasound Source	Piezoelectric	Piezoelectric	Piezoelectric
Probe Frequency	Pediatric: 5 MHz (S+ Probe)	Adults: 3.5 MHz (M+ Probe) 2.5 MHz (XL+ Probe)	Pediatric: 1 – 6 MHz (SC6-1 Probe) 4 – 15 MHz (SL15-4 Probe)
Elastography Mode	Vibration-Controlled Transient™	Vibration-Controlled Transient™	ShearWave Elastography™
Bias	(-13.5%) – (3.6%)	(-13.9%) – (1.3%)	(-7.2%) – (43.4%)[2]
Precision	(0.7%) – (2.0%)	(0%) – (3.1%)	(0%) – (3.4%)[3]

[2] Pediatric probes
[3] Pediatric probes