



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

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

September 13, 2017

Re: K172142
Trade/Device Name: FibroScan[®] 430 Mini+
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: July 7, 2017
Received: July 17, 2017

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,

A handwritten signature in blue ink, reading "Robert D. Ochs", is positioned over a large, light blue "FDA" watermark. To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K172142

Device Name
FibroScan® 430 Mini+

Indications for Use (Describe)

The FibroScan® 430 Mini+ 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® 430 Mini+ 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Diagnostic Ultrasound Intended Use

System: FibroScan® 430 Mini+

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, 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 (CAP™) et 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, 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 (CAPTM) et 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, 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 (CAPTM) et 3.5 MHz

510(K) Summary
Echosens FibroScan® 430 Mini+ System

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

Manufacturer: Echosens
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 Facsimile: +33 1 44 82 68 36

Contact Person: Zvi Ladin, Ph.D.
 Principal
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 Email: zladin@bmtadvisors.com

Date Prepared: July 7, 2017

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan® 430 Mini+

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 FibroScan® 530 Compact (#K160524) manufactured by the sponsor and cleared on March 18, 2016.

Device Description

FibroScan® 430 Mini+, 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 FibroScan® 430 Mini+ CAP (Controlled Attenuation Parameter) parameter, ranging between 100 and 400 decibels per meter (dB/m), provides an estimation of the total ultrasonic wave attenuation (forward and return paths) at 3.5 MHz, measured concomitantly with tissue stiffness.

Intended Use / Indications for Use

The FibroScan® 430 Mini+ 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® 430 Mini+ 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

The FibroScan® 430 Mini+ system is substantially equivalent to the FibroScan® 530 Compact system cleared via 510(k) #K160524. Both systems encompass a Controlled Attenuation Parameter (CAP) designed to estimate the ultrasound attenuation (forward and return paths) at the frequency of 3.5 MHz, using the M+ and XL+ transducers. Additionally, both systems provide 50Hz shear wave speed measurements and estimates of tissue stiffness.

The FibroScan® 430 Mini+ modification relates to its smaller size and conversion to a portable device. The FibroScan® 430 Mini+ system is otherwise identical to the predicate FibroScan® 530 Compact systems as related to the indications for use, operating principles, M+ and XL+ probes, materials, examination procedure, imaging modes, imaging capabilities, information processing, performance measurements, and manufacturing process.

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 2.1 2015: 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 1.1 2013-02: Ultrasonics -- Hydrophones -- Part 2: Calibration for Ultrasonic Fields up to 40 Mhz
- 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
- AAMI / ANSI / 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 tested for shear wave speed and CAP on calibrated phantoms with known elasticity and attenuation.

The shear wave speed 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 device. Results show that while the predicate FibroScan 530 Compact shear wave speed bias results reported minimum and maximum values of [-12.9%; -2.6%] for the M+ probe and [-14.3%; -2.3%] for the XL+ probe; the range of shear wave speed bias results measured with the FibroScan 430 Mini+ device had minimum and maximum values of [-13.1%; -1.1%] for the M+ probe and [-13.3%; -2.5%] for the XL+ probe. Therefore, the overall range of bias values for the shear wave speed in the predicate FibroScan 530 Compact is <11% and <12% for the M+ and XL+ probes respectively, while the corresponding values for shear wave speed in the FibroScan 430 Mini+ is ≤12% and <11% respectively, and can therefore be considered as similar to the predicate.

The CAP 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. The range of CAP bias values measured on the predicate FibroScan are [-1.5%; 4.7%] for the M+ probe and [1.4%; 3.9%] for the XL+ probe. Therefore, the overall range of bias values for CAP is <7% and <3% for the M+ and XL+ probes respectively.

The results are valid for FibroScan 430 Mini+ as the same acquisition platform model (US board and firmware) with identical ultrasound module and the same software core are used on FibroScan 530 Compact and FibroScan 430 Mini+.

Moreover, this was confirmed by the shear wave speed bias testing on FibroScan 430 Mini+ that showed no difference between both models.

The shear wave speed precision measurement, i.e. the standard deviation of the independent measurements of the shear wave speed, normalized by the reference value was evaluated and compared to the corresponding value reported for the predicate device. Results show that while the predicate FibroScan 530 Compact shear wave speed precision results reported minimum and maximum values of [0%; 0.9%] for the M+ probe and [0%; 1.5%] for the XL+ probe; the range of shear wave speed results reported for the FibroScan 430 Mini+ are [0.2%; 0.7%] for the M+ probe and [0%; 0.7%] for the XL+ probe. Therefore, the overall range of precision values for the shear wave speed in the predicate FibroScan 530 Compact is <1% and <2% for the M+ and XL+ probes respectively, while the corresponding values in the FibroScan 430 Mini+ is <1% for both probes, and can therefore be considered as better than the predicate.

The CAP precision measurement, i.e. the standard deviation of the independent measurements of the CAP, normalized by the reference value was evaluated. The range of CAP precision values measured on the predicate FibroScan are [0.6%; 1.0%] and [0.9%; 1.3%] for M+ and XL+ probes respectively. Therefore, the overall range of precision values for CAP values is <1% for both probes.

The results are valid for FibroScan 430 Mini+ as the same acquisition platform model (US board and firmware) with identical ultrasound module and the same software core are used on FibroScan 530 Compact and FibroScan 430 Mini+.

Moreover, this was confirmed by the shear wave speed precision testing on FibroScan 430 Mini+ that showed no difference between both models.

In summary, the bias and the precision of the shear wave speed measured by the FibroScan 430 Mini+ are within the same range or better than those of the predicate FibroScan 530 Compact device. Therefore, the FibroScan 430 Mini+ system was found to have a safety and effectiveness profile that is similar to the predicate FibroScan 530 Compact device.

Substantial Equivalence

The modified FibroScan® System (Model 430 Mini+) has the same intended use and indications for use, uses the same operating principle and materials, incorporates the same basic design, emits the same energy and acquires the same information as the predicate device. The differences in size, weight and internal organization of its components do not raise new or different questions of safety or efficacy.

In summary, the FibroScan® 430 Mini+ is substantially equivalent to the predicate device – the FibroScan® 530 Compact (#K160524) manufactured by the sponsor and cleared on March 18, 2016.