



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

November 14, 2017

Re: K173034

Trade/Device Name: FibroScan[®] Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+)

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYO, ITX

Dated: September 21, 2017

Received: September 28, 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.

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.

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

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)

K173034

Device Name

FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+)

Indications for Use (Describe)

The FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+) 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® Family of Products (Models: 502 Touch, 530 Compact, and 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 diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver.

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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**510(K) Summary
Echosens' FibroScan® System**

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

Manufacturer: Echosens
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Date Prepared: November 9, 2017

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan® Family of Products
(Models: 502 Touch, 530 Compact, and 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 a previously cleared FibroScan® 530 Compact System (#K160524)

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 revision of the indications for use (IFU) for the FibroScan system by Echosens. The phrase “...an aid to clinical management...” is replaced by the phrase “...an aid to diagnosis and monitoring...”

Recognized 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 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
- 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

No new hardware or software elements were included in the submission. Therefore, no new performance data were required in support of the submission.

Intended Use / Indications for Use

The FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+) 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® Family of Products (Models: 502 Touch, 530 Compact, and 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 diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver.

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 revision of the indications for use applies to all members of the FibroScan® family, including the 502 Touch, 530 Compact and 430 Mini+. All products listed in this submission were previously cleared following the premarket notification process.

Substantial Equivalence Discussion

The revised indications for use provide clarity on the clinical utilization of the FibroScan® system. Its perfect safety record and broad clinical use as an aid to the diagnosis and monitoring of adult patients with liver disease support the revision of its indications for use.

This submission did not involve changes in the hardware or software of the system, leading to the conclusion that the candidate device raises no new or different issues of safety or effectiveness.