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

July 30, 2021

Re: K212035
Trade/Device Name: FibroScan® 230
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 25, 2021
Received: June 30, 2021

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212035

Device Name
FibroScan® 230

Indications for Use *(Describe)*
The FibroScan® 230 is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. The Shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease.

The FibroScan® 230 is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 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, and CAP may be used as an aid in the 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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Special 510(K) Summary
Echosens' FibroScan® 230

K212035

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

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Date Prepared: June 25, 2021

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan® 230

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
6 rue Ferrus, Paris, France, 75014
Telephone: +33 1 44 82 78 56
Fax: +33 1 44 82 78 60

Establishment
Registration Number: 3010258456

Predicate Device

This submission claims substantial equivalence to Echosens's FibroScan® 530 Compact, cleared on March 25, 2021 (#K203273).

Device Description

FibroScan® System and its probes is an active non-implantable medical device using ultrasound and based on Vibration- Controlled Transient Elastography (VCTE™) technology. It is designed to perform non-invasivemeasurements of liver shear wave speed and estimate 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 focus of this submission is the new FibroScan® 230, which separates the FibroScan® System into two parts: a smaller equipment unit (which includes the hand-held probes) and the FibroScan® application, installed on the user's computer. The FibroScan® Application displays the user interface of the system and interacts with the equipment unit through a USB connection. The FibroScan® Application may also interact with the Echosens Cloud through an internet network. Only the FibroScan® 230 equipment and FibroScan® application are included in the FibroScan® 230 system while the Echosens cloud and the end-user computer are not part of the FibroScan® 230 medical device.

Comparison of Technological Characteristics

The FibroScan® 230 system is substantially equivalent to the FibroScan® 530 Compact system cleared by 510(k) #K203273. Both systems provide 50Hz shear wave speed measurements and estimates of tissue stiffness in the liver using the S+, M+, and XL+ transducers. Additionally, 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.

The FibroScan® 230 modification relates to its design configuration and therefore includes structural differences in system design software architecture and electronic architecture (e.g., no integrated touchscreen). The FibroScan® 230 system liver measurement is otherwise identical to the predicate FibroScan® 530 Compact system as related to the intended use and indications for use, same operating principle and materials, same S+, M+, and XL+ probes, emits the same energy, same examination procedure, acquires the same information, applies the same signal processing and imaging modes, displays the same information, performance measurements, and manufacturing process. Therefore, the design changes related to FibroScan® 230 do not impact the liver examination. Table 1 provides a detailed comparison of the candidate and predicate devices.

As with the predicate device, the CAP (previously called CAPc) and SmartDepth options are enabled with the 'SmartExam' capability. The SmartDepth automatically adapts the depth of the liver stiffness measurement (LSM) based on the anatomy of the patient and is available for M+ and XL+ probes while CAP is available for S+, M+, and XL+ probes. The LSM and CAP calculated with the SmartDepth capability uses the same algorithm as the predicate system.

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: Medical Electrical Equipment - Part 2-37: Particular Requirements for The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment; Edition 2.1 2015.
- NEMA UD: Acoustic Output Measurement Standard for Diagnostic Ultrasound EquipmentRevision 3; 2-2004 (R2009).
- IEC 62127-1: Ultrasonics -- Hydrophones -- Part 1: Measurement and Characterization ofMedical Ultrasonic Fields Up To 40 Mhz; Edition 1.1 2013-02.
- IEC 62127-2: Ultrasonics -- Hydrophones -- Part 2: Calibration for Ultrasonic Fields Up To40 Mhz; Edition 1.1 2013-02.
- IEC 62127-03: Ultrasonics -- Hydrophones -- Part 3: Properties of Hydrophones for Ultrasonic Fields Up To 40 Mhz; Edition 1.1 2013-05.
- IEC 61161: Ultrasonics -- Power Measurement -- Radiation Force Balances and Performance Requirements; Edition 3.0 2013-01.
- AAMI / ANSI ES60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, Mod); 2005/(R) 2012
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests; Edition 4: 2014-02.
- IEC 60601-1-6: Medical Electrical Equipment - Part 1-6: General Requirements For BasicSafety And Essential Performance - Collateral Standard: Usability; Edition 3.1 2013-10
- IEC 62366-1 Edition 1.0 2015-02: Medical Devices - Application Of Usability Engineering To Medical Devices.
- IEC 62304: Medical Device Software - Software Life Cycle Processes; First Edition 2006-05, Equivalent to IEC 62304: 2006/A1:2016.
- ISO 14971 Second: Medical Devices - Application Of Risk Management To Medical Devices; Edition 2007-03-01.

Intended Use / Indications for Use

The FibroScan® 230 is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. The shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease.

The FibroScan® 230 is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 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, and CAP may be used as an aid in the clinical management of pediatric patients with liver disease.

Performance Data

The FibroScan® 230 effectiveness was evaluated in terms of its bias and precision in measuring liver shear wave speed (m/s) and CAP, using the S+, M+ and XL+ probes. Both a comparison with the predicates' documented performance (as presented in K203273) and a direct comparison of the measurement accuracy between the proposed and cleared systems were performed.

Direct comparison refers to testing the predicate and candidate device contemporaneously using the same probes, phantoms, and experimental setup, thereby controlling for environmental conditions (temperature, humidity), imperfections in the materials and manufacturing process leading to sample inhomogeneities, as well as the viscoelastic properties of the materials used to construct the phantoms which may lead to changes in their stiffness values.

The shear wave speed bias measurement and the precision measurement was evaluated and compared to the documented corresponding value reported for the predicate device. Results show that, for liver examination, the bias and precision measurements of the candidate FibroScan® 230 system and the predicate FibroScan® 530 Compact system documented similar performance. Specifically, the ranges of the bias values documented for the candidate are substantially equivalent to the ranges of the bias values documented for the predicate device (4.9% – 14.6% for the candidate and 0.5% – 12.6% for the predicate) and the precision values documented for the candidate are very similar to the ranges of the precision values documented for the predicate device.

Direct comparison of the CAP results, using dynamic testing (>200 measurements) on multiple spots demonstrated the range and mean values of CAP bias were substantially equivalent to the bias of the CAP in the candidate device (range of 1.4% – 11.1% for the candidate CAP dynamic testing and 1.8% – 10.1% for the predicate). In addition, the range and mean values of CAP precision values were equivalent to the precision of the CAP in the candidate device.

An additional direct comparison between the candidate and predicate devices showed that the bias values for the shear wave speed and CAP were shown to be comparable (under 5% difference) between FibroScan® 230 and FibroScan® 530 Compact. Therefore, the proposed systems have substantially equivalent effectiveness in measuring shear wave speed and CAP bias.

Furthermore, the stiffness and CAP measurement ranges, as well as the SmartDepth ranges, have been verified on the FibroScan® 230 system and are the same as the predicate device.

In summary, the bias and the precision of the shear wave speed and the CAP measured by the FibroScan® 230 are within the same ranges as those of the predicate FibroScan® 530 Compact cleared in K203273 and, therefore, considered substantially equivalent.

Clinical Data

No clinical data was required for this submission.

Substantial Equivalence Discussion

The FibroScan® 230 includes the same intended use and indications for use, uses the same operating principle and materials, emits the same energy and acquires the same information as the predicate FibroScan® 530 Compact device (K203273). The separation of the system unit from the FibroScan® application, installed on the user's computer, do not raise new or different questions of safety or efficacy.

The candidate device was demonstrated to be substantially equivalent to its predicate device FibroScan® 530 (K203273) based on the aforementioned verification and validation studies.

Conclusion

The conclusions drawn from the clinical and nonclinical information provided in this submission demonstrate that FibroScan® 230 is as safe, as effective, and performs as well as the legally marketed device predicate. The FibroScan® 230 raises no new or different issues of safety or effectiveness and is substantially equivalent to its predicate device.

Table 1. Comparison of FibroScan® 230 to FibroScan® 530 Compact Predicate

	FibroScan® 530 Compact	**FibroScan® 230**
510(k) # (Clearance)	K203273 (March 25, 2021)	Candidate Device TBD
Manufacturer	Echosens	Echosens
Indications for Use	The FibroScan® is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. The Shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease. The FibroScan® is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 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, and CAP may be used as an aid in the clinical management of pediatric patients with liver disease.	
Application	Abdominal	Abdominal
Imaging Modes	A-mode / M-mode Transient Elastography/ Shear Wave / (CAP™)	A-mode / M-mode Transient Elastography/ Shear Wave / (CAP™)
Ultrasound	Piezoelectric ultrasound source	Piezoelectric ultrasound source
Probes	M+-probe (3.5 MHz) XL+ probe (2.5 MHz) S+ probe (5 MHz) (single element ultrasound transducer)	M+-probe (3.5 MHz) XL+ probe (2.5 MHz) S+ probe (5 MHz) (single element ultrasound transducer)
Depth Analysis Method	Fixed Depth: S1 exam : 15-40 mm S2 exam : 20-50 mm Adaptive Depth (SmartDepth): M exam: 25-65 / 30-70 mm XL exam: 35-75 mm/ 40-80 mm/ 45-85 mm	Fixed Depth: S1 exam : 15-40 mm S2 exam : 20-50 mm Adaptive Depth (SmartDepth): M exam: 25-65 / 30-70 mm XL exam: 35-75 mm/ 40-80 mm/ 45-85 mm
VCTE™ Mode	Shear wave speed measurements and tissue stiffness	Shear wave speed measurements and tissue stiffness
VCTE™ Range	Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa)	Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa)
VCTE™ Display	Shear wave speed and stiffness medians and IQR/median ratio	Shear wave speed and stiffness medians and IQR/median ratio

Attenuation Mode	Controlled Attenuation Parameter (CAP)	Controlled Attenuation Parameter (CAP)
Attenuation Range	CAP value (100-400 dB/m)	CAP value (100-400 dB/m)
Attenuation Display (Second generation/ Enhanced CAP)	CAP mean and standard deviation	CAP mean and standard deviation
Attenuation Display – Probes compatibility	S+ Probe M+ Probe XL Probe	S+ Probe M+ Probe XL Probe
Size and Weight	460 mm x 360 mm x 250 mm (H x W x D) 10kg with accessories	265.5mm x 157mm x 200mm (H x W x D) 4.4kg with accessories
Power supply	100-240 V ~ 50–60 Hz	100-240 V ~ 50–60 Hz
Core Component	Elastography engine Analog front end High frequency (US): PV3 Analog front end Low frequency (servo control): PV3	Elastography engine Analog front end High frequency (US): PV3 Analog front end Low frequency (servo control): PV3
Operating system	Windows 10 Embedded	Windows 10 Embedded
Screen	Color LCD touch screen, 15-inch.	User's computer (Screen resolution req: 1024 x 768)
Internet	Internet connection included as a feature	An Internet connection is required prior to first usage
Battery	ARTS Energy (ref. 4 INR19/66-2) Part number 806957 / M300002	N/A
Accessories	Roll Stand 530	N/A

The following abbreviations are used in the table: US – Ultrasound; IQR – Interquartile Range, VCTE™ -- Vibration Controlled Transient Elastography