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

July 16, 2020

Re: K200655
Trade/Device Name: FibroScan® 630
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 19, 2020
Received: June 23, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200655

Device Name
FibroScan® 630

Indications for Use *(Describe)*
The FibroScan® 630 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.

FibroScan® 630 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 may be used as an aid in the clinical management of pediatric patients with liver disease.

FibroScan® 630 (Expert) is also indicated for noninvasive measurement in the spleen of 100 Hz shear wave speed and estimates of stiffness that may be used as an aid to diagnosis, monitoring and clinical management of adult patients with liver disease, as part of an overall assessment of the liver.

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® 630

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 (liver) Abdominal (spleen)	N[i] N[i]	P N[i]					P 1, 2, 3 N4[i]
	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
4. Vibration Controlled Transient Elastography at 100 Hz

[i] Option available for FibroScan 630 Expert only

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

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 (liver) Abdominal (spleen)		P N[i]					P 1, 2, 3 N4[i]
	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
4. Vibration Controlled Transient Elastography at 100 Hz

[i] Option available for FibroScan 630 Expert only

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 (CAP™) et 3.5 MHz

Diagnostic Ultrasound Intended Use

Transducer: ES-C5-2R60S-3

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	N[i]						
	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

[i] Option available for FibroScan 630 Expert only

510(K) Summary
Echosens' FibroScan® 630

K200655

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

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Date Prepared: March 9, 2020

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan® 630

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 a combination of three previously cleared devices:

1. Predicate device: Echosens's FibroScan® Family of Products (Models: 502 Touch, 530 Compact, And 430 Mini+) (K181547), cleared on July 9, 2018;
2. Reference device: Supersonic Imagine's Aixplorer & Aixplorer Ultimate Ultrasound Diagnostic Systems (K173021), cleared on January 9, 2018; and
3. Reference device: Telemed's MicrUs (K161968), cleared on November 3, 2016.

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/spleen 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/spleen. 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 new FibroScan® 630, available in two configurations: FibroScan® 630 'Prime' (FS630P) and FibroScan® 630 'Expert' (FS630E). Both FS630P and FS630E include improvements of the FibroScan appearance and user interface.

The FS630P version has the same indications as the previously cleared models and is only indicated for non-invasive measurement of 50 Hz shear wave speed in the liver and estimates of its stiffness, as well as determination of a 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The FS630E includes an expansion of the intended use to include noninvasive measurement of shear wave speed at 100Hz in the spleen and estimates of its stiffness as well as an inclusion of a B-Mode ultrasound imaging system to help the user locate the liver or spleen.

Comparison of Technological Characteristics

The FibroScan® 630 system is substantially equivalent to the FibroScan® 530 Compact system cleared by 510(k) #K181547. 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® 630 modification relates to its size, weight, power, and electronics. The FS630E also includes modifications related to its software in order to accommodate the B-mode module and allow spleen stiffness measurement. The FibroScan® 630 system liver measurement is otherwise identical to the predicate FibroScan® 530 Compact system as related to the indications for use, operating principles, S+, M+, and XL+ probes, materials, examination procedure, imaging modes, imaging capabilities, information processing, performance measurements, and manufacturing process.

No new hardware elements were included in the submission apart from the addition of the localization ultrasound system, previously cleared by Telemed in 510(k) #K161968.

Similar to liver stiffness measurement (LSM), spleen stiffness measurement (SSM) using FibroScan® 630 Expert relies on VCTE™ method. As the spleen is stiffer and smaller than the liver, specific characteristics of the spleen stiffness examination were modified:

- Elastic shear wave at a controlled 100 Hz center frequency
- Ultrasound pulse repetition frequency of 8000 Hz
- Peak-to-peak amplitude of the vibration reduced to 1 mm-PP

- Target tissue depths of 25 - 55 mm
- Stiffness value range between 6.0 and 100.0 kPa

Unlike LSM that can be measured with S+, M+ and XL+ probes, SSM can only be measured with the FibroScan® M+ probe.

The technological characteristics of FibroScan® 630 Expert are substantially equivalent to those of the Aixplorer® (#K173021), which is also indicated for measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen. Both devices are based on the same physical phenomenon, namely the effect of the mechanical properties of soft tissue on the propagation of low frequency mechanical waves in internal organs. Both use ultrasound for measuring the changes in the strain field that result from the propagation of the mechanical wave and display the processed values of shear wave speed. Therefore, the candidate and the predicate and reference devices are substantially equivalent in terms of the technology used.

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 Equipment Revision 3; 2-2004 (R2009).
- IEC 62127-1: Ultrasonics -- Hydrophones -- Part 1: Measurement And Characterization Of Medical Ultrasonic Fields Up To 40 Mhz; Edition 1.1 2013-02.
- IEC 62127-2: Ultrasonics -- Hydrophones -- Part 2: Calibration For Ultrasonic Fields Up To 40 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 Basic Safety 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® 630 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.

FibroScan® 630 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 may be used as an aid in the clinical management of pediatric patients with liver disease.

FibroScan® 630 (Expert) is also indicated for noninvasive measurement in the spleen of 100 Hz shear wave speed and estimates of stiffness that may be used as an aid to diagnosis, monitoring and clinical management of adult patients with liver disease, as part of an overall assessment of the liver.

Performance Data

The accuracy and precision of the device was tested for shear wave speed of the liver and the spleen on calibrated phantoms with known elasticity and attenuation. In addition, to allowed direct comparison of the measurement accuracy between the proposed and cleared systems, same sample of phantoms were tested contemporaneously by the candidate and predicate FibroScan systems, using the same probes and the same phantoms.

The shear wave speed bias, i.e. the difference in the mean shear wave speed measured and the nominal shear wave speed of the phantom, normalized by the nominal shear wave speed and expressed in percent was evaluated and compared to the corresponding value reported for the predicate device.

For liver examination, results show that while the predicate FibroScan® 530 Compact shear wave speed bias results reported minimum and maximum values of [-13.9%; 3.6%] for the S+ probe, [-12.9%; -2.6%] for the M+ probe and [-14.3%; -3.4%] for the XL+ probe; the range of shear wave speed bias results measured with the candidate FibroScan device had minimum and maximum values of [-20.6%; -6.5%] for the S+ probe, [-17.5%; -7.6%] for the M+ probe and [-17.5%; -7.7%] for the XL+ probe. Therefore, the overall range of bias values for the shear wave speed in the predicate FibroScan® 530 Compact is ≤17.5%, <11% and <11% for the S+ M+ and XL+ probes

respectively, while the corresponding values for shear wave speed in the FibroScan® 630 is ≤14.1%, <10% and <10% respectively, and can therefore be considered as equivalent to the predicate. Moreover, the bias values for the shear wave speed and CAP on the same probes, phantoms and experimental setup using the predicate and candidate devices lead to the conclusion, that the proposed system (FibroScan® 630) is as effective as its predicate (FibroScan® 530) in measuring shear wave speed and CAP bias.

The sheer 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.

For liver examination, results show that while the candidate device documented the range of shear wave speed precision measured for the S+ [0%; 2%], M+ [0%; 2%] and XL+ [0%; 1%] probes. The corresponding minimum and maximum values for the predicate are [0.2%; 1.6%] for S+ probe, [0%; 0%] for the M+ probe and [0%; 1.5%] for the XL+ probe. Therefore, the overall range of precision values for the shear wave speed in the predicate FibroScan® 530 Compact is <2%, <1% and <2% for the S+ M+ and XL+ probes respectively, while the corresponding values in the FibroScan® 630 is ≤2%, ≤2% and ≤1% respectively, and can therefore be considered as equivalent to the predicate.

For spleen examination, the range of shear wave speed bias results measured by the candidate FibroScan device had minimum and maximum values of [-24%; -17%] for the M+ probe. Therefore, the overall range of bias values for the shear wave speed in the candidate FibroScan is 7% for the M+ probe. This value is similar to the range of 9.9% documented for the candidate device and 10.3% obtained in the verification of the predicate device for liver measurements. Moreover, the range of shear wave speed precision results measured with the candidate FibroScan device had minimum and maximum values of [0%; 1%] for the M+ probe. Therefore, the overall range of precision values for the shear wave speed in the candidate FibroScan is 1% for the M+ probe. This is similar to the values of 2% and 0% measured for the candidate and predicate devices for liver measurements.

In summary, the bias and the precision of the shear wave speed measured by the FibroScan® 630 are within the same range than those of the predicate FibroScan® 530 Compact device. Furthermore, the direct comparison (i.e., same probes, phantoms and experimental setup) of the candidate system and its predicate lead to the conclusion that the FibroScan® 630 system was found to have a safety and effectiveness profile that is similar to the predicate FibroScan® 530 Compact device.

In addition to bench testing, clinical information was submitted to provided support for the expanded indications for use for spleen stiffness measurement.

Clinical Data

The performance of FibroScan® 100 Hz sheer wave speed for spleen stiffness estimates was assessed in a prospective, multi-center, non-randomized study. The device was used to perform a spleen stiffness examination in each patient using the settings of the novel spleen examination (100 Hz), and the standard liver examination (50 Hz). Study objectives also included evaluating the 100 Hz SSM in comparison to hepatic venous pressure gradient (HVPG) and other non-invasive tests (NITs). The study included 260 patients with chronic liver disease (169 male; 91 female) with a median age of 59 (range 51 – 68) and a median BMI of 26 kg/m^2 (range 23.7 – 28.6). Patients with chronic liver disease due to hepatitis virus C (155 patients), hepatitis virus B (19 patients), or alcoholic liver diseases (79 patients) were enrolled. Patients had ultrasound examination, blood examination, and esophagogastroduodenoscopy (EGD) performed within 6 months of the spleen stiffness measurement (SSM). The examination was performed with the patient lying in supine position with left arm in maximal abduction, and the probe placed in the left intercostal spaces. The median liver stiffness measurement was 46.2 kPa and the median SSM was 48 kPa. The novel 100 Hz spleen-dedicated FibroScan® settings demonstrated significantly higher success rate than the 50 Hz measurements (92.5% compared to 76.0%, P <.001). No adverse events were reported in this study.

An ancillary study to examine intra-operator and inter-operator reproducibility, including 10 cirrhotic patients, 10 non-cirrhotic patients, and 6 healthy subjects showed good intra-class and inter-class reproducibility (0.94 and 0.96, respectively). In cirrhotic patients the intra-class and inter-class coefficient correlations were higher (0.96 and 0.97, respectively) than in non-cirrhotic patients and healthy subjects, potentially due to larger spleen diameters in cirrhotic patients.

Substantial Equivalence Discussion

The FibroScan® 630 uses the same operating principle and materials, incorporates the same basic design, emits the same energy and acquires the same information as the predicate FibroScan® 530 device (K181547). The differences in size, weight and internal organization of its components do not raise new or different questions of safety or efficacy. The FS630P also includes the same intended use and indications for use as the predicate device.

The addition of the spleen stiffness indication for the FS630E was demonstrated to be substantially equivalent to its predicate device FibroScan® 530 (K181547) and Aixplorer Ultimate Ultrasound Diagnostic Systems (K173021), as they both have the same intended use, indications for use, and the technological differences do not raise different issues of safety and effectiveness. A comprehensive literature review and a large clinical study demonstrated the device's safety and effectiveness in measuring spleen stiffness. Furthermore, the inclusion of a B-Mode ultrasound imaging system (OEM previously cleared by Telemed under K161968) to help the user locate the liver or spleen is operating in compliance with its intended use, indications for use and FDA-cleared labeling.

In summary, the conclusions drawn from the clinical and nonclinical information provided in this submission demonstrate that FibroScan® 630 raises no new or different issues of safety or effectiveness and is substantially equivalent to its predicate devices.

	FibroScan® 630 (TBD; Submission Device)	FibroScan® 530 Compact #K181547 (July 9, 2018)	Aixplorer® #K173021 (January 9, 2018)
Manufacturer	Echosens	Echosens	SuperSonic Imagine, S.A.
Indications for Use	The FibroScan® 630 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. FibroScan® 630 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 may be used as an aid in the clinical management of pediatric patients with liver disease. FibroScan® 630 (Expert) is also indicated for noninvasive measurement in the spleen of 100 Hz shear wave speed and estimates of stiffness that may be used as an aid to diagnosis, monitoring and clinical management of adult patients with liver disease, as part of an overall assessment of the liver.	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 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 may be used as an aid in the clinical management of pediatric patients with liver disease.	The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging, doppler fluid flow analysis of the human body. The SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems are indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac. In addition, the SuperSonic Imagine AIXPLORER® & AIXPLORER® Ultimate ultrasound diagnostic systems and associated transducers are intended for:- Measurements of abdominal anatomical structures,- Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,- Measurements of brightness ratio between liver and kidney,- Visualization of abdominal vascularization, microvascularization and perfusion,- Quantification of abdominal vascularization and perfusion. The shear wave speed and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion, the quantification of vascularization and perfusion may be used as an aid to clinical management of adult patients with liver disease.

Clinical Application	Abdominal; FS630P: Shear wave speed, stiffness, and coefficient of attenuation in the liver FS630E: Shear wave speed, and stiffness, in the liver and the spleen and coefficient of attenuation in the liver	Abdominal; Shear wave speed, stiffness, and coefficient of attenuation in the liver	Abdominal; Shear wave speed, and tissue stiffness in the liver and the spleen
Imaging modes	A-mode M-mode B-mode (FS630E only for organ localization) Transient Elastography / Shear Wave	A-mode M-mode Transient Elastography / Shear Wave	B-mode ShearWave™ Elastography
Ultrasound Source	Piezoelectric ultrasound source	Piezoelectric ultrasound source	Piezoelectric ultrasound source
Probe	M+ VCTE probe (3.5 MHz)* XL+ VCTE probe (2.5 MHz) S+ VCTE probe (5.0 MHz) ES-C5-2R60S-3 convex array (3.5 MHz) (FS630E only)** (single element ultrasound transducer) *M+ Probe is only probe used for Spleen (FS630E only) ** OEM MicrUs EXT-1H (#K161968)	M+ VCTE probe (3.5 MHz) XL+ VCTE probe (2.5 MHz) S+ VCTE probe (5.0 MHz) (single element ultrasound transducer)	SC6-1 (3.5 MHz) (1 – 6 MHz curved array transducer)
Elastography mode	Vibration-controlled Transient Elastography™	Vibration-controlled Transient Elastography™	ShearWave™ Elastography
Source of Mechanical Vibration	External electromechanical Vibrator	External electromechanical Vibrator	Radiation force in ShearWave™ Elastography
Shear Wave Speed Determination	Post-processing	Post-processing	Post-processing
Elastography Display	**Liver:** Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa) Interquartile range (IQR) and IQR/median ratio **Spleen: (FS630E only)** Shear wave speed (1.4-5.8 m/s) Stiffness (6.0-100 kPa) for spleen Interquartile range (IQR)	**Liver:** Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa) Interquartile range (IQR) and IQR/median ratio	2D color coded shear wave speed map (elastogram)

Controlled Attenuation Parameter (CAP)	Available for M+ and XL+ Probes only for liver	Available for M+ and XL+ Probes	N/A
CAP Display	CAP value (100-400 dB/m) and interquartile range (IQR)	CAP value (100-400 dB/m) and interquartile range (IQR)	N/A
Bias (Liver)	S+: (-20.6%) – (-6.5%) M+: (-17.5%) – (-7.6%) XL+: (-17.5%) – (-7.7%)	S+: (-13.9%) – (3.6%) M+: (-12.9%) – (-2.6%) XL+: (-14.3%) – (3.4%)	(-9.4%) – (43.4%)
Bias (Spleen) FS630E Only	M+: (-24%) – (-17%)	N/A	
Precision (Liver)	S+: (0%) – (2%) M+: (0%) – (2%) XL+: (0%) – (1%)	S+: (0.2%) – (1.6%) M+: (0%) – (0%) XL+: (0%) – (1.5%)	(0%) – (3.9%)
Precision (Spleen) FS630E Only	M+: (0%) – (1%)	N/A	

Table 1. Predicate Device Comparison for FibroScan® 630