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

July 9th, 2018

Re: K181547
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: June 1, 2018
Received: June 12, 2018

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.

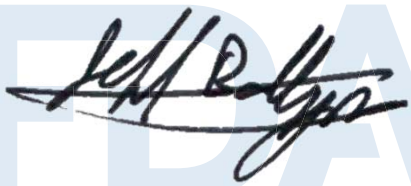
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

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)*
K181547

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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# 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™) at 3.5 MHz

# Diagnostic Ultrasound Intended Use

System: FibroScan® 530 Compact

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™) at 3.5 MHz

# 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 | | 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® 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

**510(K) Summary**
**Echosens' FibroScan® 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 4, 2018

**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 combination of two previously cleared devices:

1. Echosens's FibroScan® Family of Products (#K173034) cleared on November 14, 2017; and
2. Echosens's FibroScan® System (#K150239) cleared on September 1, 2015.

**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 addition of the S+ probe to models FibroScan® 530 Compact and FibroScan® 430 Mini+. The S+ probe addresses a smaller anatomic size of pediatric patients, while using 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. In addition, the S+ probe developed for the 530 Compact and 430 Mini+ models is similar to the S+ probe cleared for the FibroScan® 502 Touch model of the FibroScan® Family of Products.

**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 3: 2007-03.
- 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.
- ISO 14971 Second: Medical Devices - Application Of Risk Management To Medical Devices; Edition 2007-03-01.

**Performance Data**

The S+ probe underwent verification tests with the FibroScan® 530 Compact and FibroScan® 430 Mini+ systems to ensure that there were no new issues regarding safety and effectiveness. Software updates were verified through system tests and did not raise any concerns regarding safety or effectiveness.

**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 addition of the S+ probe applies to models 530 Compact and 430 Mini+ of the FibroScan® family of products. The S+ probe was previously cleared for the 502 Touch model, following the premarket notification process (#K150239). The FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+) is otherwise identical to the predicate FibroScan® Family of Products (#K173034) 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.

**Substantial Equivalence Discussion**

The modified FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 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 (#K173034). In addition, the S+ probe has the same operating principle and materials, incorporates the same basic design, emits the same energy and acquires the same information as the S+ probe cleared in the predicate device (#K150239).

The S+ probe underwent hardware and software verification tests with the FibroScan® 530 Compact and FibroScan® 430 Mini+ systems to ensure that the candidate device raises no new or different issues of safety and effectiveness.

In summary, the FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+) is substantially equivalent to the predicate devices.

| | **FibroScan® 530 Compact (Submission Device Model)** | **FibroScan® 430 Mini+ (Submission Device Model)** | **FibroScan® 502 Touch (Predicate)** |
|---|---|---|---|
| **510(k) # (Clearance Date)** | TBD<br><br>Clearances:<br>K173034 (November 14, 2017)<br>K160524 (March 18, 2016) | TBD<br><br>Clearances:<br>K173034 (November 14, 2017)<br>K172142 (September 13, 2017) | Clearances:<br>K173034 (November 14, 2017)<br>K150239 (September 1, 2015)<br>K150949 (June 3, 2015)<br>K123806 (April 5, 2013) |
| **Manufacturer** | Echosens | Echosens | Echosens |
| **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.<br><br>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.<br>Shear wave speed and stiffness may be used as an aid in the clinical management of pediatric patients with liver disease. | | |
| **Clinical Application** | Pediatric | Pediatric | Pediatric |
| **Imaging modes** | A-mode<br><br>M-mode<br><br>Transient Elastography / Shear Wave | A-mode<br><br>M-mode<br><br>Transient Elastography / Shear Wave | A-mode<br><br>M-mode<br><br>Transient Elastography / Shear Wave |
| **Ultrasound Source** | Piezoelectric ultrasound source | Piezoelectric ultrasound source | Piezoelectric ultrasound source |
| **Probe** | S+ Probe (5 MHz)<br><br>(single element ultrasound transducer) | S+ Probe (5 MHz)<br><br>(single element ultrasound transducer) | S+ Probe (5 MHz)<br><br>(single element ultrasound transducer) |
| **Elastography mode** | Vibration-controlled Transient Elastography™ | Vibration-controlled Transient Elastography™ | Vibration-controlled Transient Elastography™ |
| **Source of Mechanical Vibration** | External electromechanical Vibrator | External electromechanical Vibrator | External electromechanical Vibrator |

| | | | |
|---|---|---|---|
| **Shear Wave Speed Determination** | Post-processing | Post-processing | Post-processing |
| **VCTE mode** | Shear wave speed measurements and tissue stiffness | Shear wave speed measurements and tissue stiffness | Shear wave speed measurements and tissue stiffness |
| **VCTE display** | Shear wave speed (0.8-5.0 m/s)<br>Stiffness (2.0-75 kPa)<br>Interquartile range (IQR) and IQR/median ratio | Shear wave speed (0.8-5.0 m/s)<br>Stiffness (2.0-75 kPa)<br>Interquartile range (IQR) and IQR/median ratio | Shear wave speed (0.8-5.0 m/s)<br>Stiffness (2.0-75 kPa)<br>Interquartile range (IQR) and IQR/median ratio |
| **Controlled Attenuation Parameter (CAP)** | Not available for S+ Probe | Not available for S+ Probe | Not available for S+ Probe |
| **Bias**[1] | (-14.3%) – (3.6%) | (-13.7%) – (0.5%) | (-13.5%) – (3.6%) |
| **Precision**[1] | (0.2%) – (1.9%) | (0.0%) – (1.6%) | (0.7%) – (2.0%) |

*Table 1. Predicate Device Comparison for FibroScan® S+ Probe*

[1] Values obtained with CIRS phantoms E-1493-1 and E-1493-2.