510 (k) SUMMARY

APR 5 2013

Echosens' FibroScan® System

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

Manufacturer: Echosens SA
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75013 Paris – France
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Date Prepared: February 28, 2012

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan®

Common Name: Diagnostic Ultrasound System and Accessories

Classification:

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 SA
30 Place d'Italie
75013 Paris – France
Telephone: +33 1 44 82 78 50
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Establishment Registration Number: N/A

Owner/operator number: N/A

Predicate Device
Aixplorer®, manufactured by SuperSonic Imagine, S.A. of Aix-en-Provence, France, cleared on August 28, 2012 under 510(k) #K112255.

Intended Use / Indications for Use
FibroScan® is intended to provide 50Hz shear wave velocity measurements through internal structures of the body.

FibroScan® is indicated for noninvasive measurement of shear wave speed at 50 Hz in the liver. The shear wave speed may be used as an aid to clinical management of patients with liver disease.

Technological Characteristics
FibroScan® uses transient elastography for the non-invasive measurement of liver shear wave speed. 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 wave and to measure its speed, which is correlated with the elasticity of the liver.

Performance Data
Non-clinical testing to assure compliance with electrical safety, electromagnetic interference standards and ultrasound standards was performed. The accuracy and precision of the device was documented based on tests performed on phantoms with known elasticity. The 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. While the predicate device reported values of bias between (-9.4%) and (43.4%), the range of bias values measured for the candidate device were between (-13.9%) and (1.3%). Therefore, the overall range of bias values for the predicate device are ~50% of the nominal shear wave speed, the corresponding range for the candidate device is < 20%. Hence, the candidate device has a bias value that is similar or better than that of the predicate device.

Similarly, the system's precision, i.e. the standard deviation of the individual measurements of shear-wave speed, normalized by the reference value was calculated. The range of values reported for the predicate device were between (0%) and (3.9%), while the corresponding range for the candidate device was between (0%) and (3.1%). Therefore, the precision of both systems is similar – range of precision values of ~4% for the predicate device and ~3% for the candidate device.

Published reports documented a high level of measurement reproducibility. For example, in a cohort of 200 patients with chronic liver disease of various etiologies Fraquelli et al. reported (Gut, 2007. 56(7):968-73) intraclass correlation coefficient of 0.98 both within and between operators, demonstrating a high level of inter- and intra-operator agreement.

Substantial Equivalence
The technology used in the candidate and predicate devices is based on elastography. The systems display the same physical variable (shear wave speed), and therefore the devices are substantially equivalent in their basic technology and its implementation. The accuracy and precision of the device were found to be substantially equivalent to those of the predicate device. Therefore, the device raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

ECHOSENS
C/O ZVI LADIN, PHD
BOSTON MEDTECH ADVISORS, INC.
990 WASHINGTON STREET, SUITE 204
DEDHAM MA 02026

Re: K123806
Trade/Device Name: FibroScan
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: March 7, 2013
Received: March 13, 2013

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.

This determination of substantial equivalence applies to the following transducers intended for use with the FibroScan, as described in your premarket notification:

Transducer Model Number

M^+
XL^+

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 Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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.

If you have any questions regarding the content of this letter, please contact Brendan O'Leary at (301) 796-6898.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K123806

Device Name: FibroScan®

Indications for Use: The FibroScan® system is intended to provide 50Hz shear wave speed measurements through internal structures of the body.

FibroScan® is indicated for noninvasive measurement of shear wave speed at 50 Hz in the liver. The shear wave speed may be used as an aid to clinical management of patients with liver disease.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123806

Indications for Use

Diagnostic Ultrasound Intended Use

System: FibroScan® 502 Touch

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					N 1, 2
	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

Indications for Use

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		N					N 1, 2
	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

Indications for Use

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		N					N 1, 2
	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

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123806