U.S. FOOD & DRUG ADMINISTRATION

E-Scopics
Claude Cohen-Bacrie
CEO
931 Chemin De La Bosque D'Antonelle
Aix-en-Provence, PACA 13090
France

Re: K213102 January 25, 2022
Trade/Device Name: ES1 System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX

Dear Claude Cohen-Bacrie:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter for your device cleared on January 11, 2022. Specifically, FDA is updating this SE letter due to a typo in the clearance date, which was incorrectly dated as January 11, 2021.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jessica Lamb, OHT7: Office of In Vitro Diagnostics and Radiological Health,

Sincerely,

Jessica Lamb
Assistant 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

E-Scopics
% Claude Cohen-Bacrie, CEO
931 chemin de la Bosque d'Antonelle
13090 Aix-en-Provence
FRANCE

January 11, 2021

Re: K213102
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Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 3, 2021
Received: December 9, 2021

Dear Claude Cohen-Bacrie:

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 and Part 809); 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,

Jessica Lamb

Jessica Lamb, Ph.D.
Assistant 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)*
K213102

Device Name
ES1 System

Indications for Use *(Describe)*

The ES1 Ultrasound Diagnostic System is intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging of the human body and provides measurements of shear wave speed and tissue stiffness, ultrasound beam attenuation and estimates of speed of sound, in internal structures of the body. This device is intended to be used by trained healthcare professionals, in a healthcare environment.

The ES1 Ultrasound Diagnostic System is indicated for imaging of anatomical structures in the abdomen and measurements of physical properties in the liver and the spleen.

In particular, the ES1 ultrasound diagnostic system is intended to provide:
- Linear distance measurements of anatomical structures,
- Measurement of shear wave speed at selected shear wave frequencies, and estimates of tissue stiffness in the liver and the spleen,
- Estimates of ultrasound attenuation coefficient in the liver at 3.5 MHz,
- Measurement of brightness ratio between structures and in particular between the liver and the kidney,
- Estimates of speed of sound in the liver.

The shear wave speed measurements, ultrasound beam attenuation, elastic properties estimates, brightness ratio may be used as an aid to the diagnosis, monitoring and clinical management of adult and 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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Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements detailed in 21 CFR 807.92

The assigned 510(k) number is: K213102

Company: E-Scopics
931 chemin de la Bosque d'Antonelle
13090 Aix-en-Provence
France

Telephone: + (33) 6 84 32 32 75

Contact Person: Claude COHEN- BACRIE

Date Prepared: 03rd January 2022

Device Names:

Trade/Proprietary Name: ES1 System
Common or Usual Name: Diagnostic Ultrasound System and Accessories
Device Class Classifications: Class II

§892.1550 : Ultrasonic pulsed doppler imaging system (IYN)
§892.1560 : Ultrasonic Pulsed Echo Imaging System (IYO)
§892.1570 : Diagnostic Ultrasound Transducer (ITX)

Substantially Equivalent/Predicate Devices:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :
Predicate Device: FibroScan® Family of Products (K203273), cleared on 03/25/2021.
Reference Devices: AIXPLORER® MACH 20 & 30 Ultrasound Diagnostic Systems (K191007), cleared on 10/25/2019.

Device description:
E-Scopics' ES1 System is an ultraportable ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging and quantitative imaging studies. The ES1 System consists of a Software App (running on a consumer off-the-shelf Selected Host) and an accessory curved array probe. The system produces images and quantifications, which are displayed on the monitor of the Selected Host. The ES1 System is operated from the Selected Host multi-touch screen. The ES1 System also allows the user to perform measurements, to capture images, and to generate printable reports.

The ES1 System is designed to perform non-invasive measurements of liver/spleen shear wave speed and to estimate tissue stiffness. The e.C5-1 probe is equipped with a mechanical vibrator to produce shear waves in tissue. When used on the liver or the spleen applications, shear waves travel through the skin and intercostal space into the abdominal organ. 2D ultrasound is used to track the shear wave and measure its speed. The system then provides an estimate of tissue stiffness. In addition, the ES1 System is designed to measure several quantitative parameters from B Mode imaging: ultrasound attenuation, speed of sound, and compute ultrasound brightness ratio between 2 regions in the image. The results of ES1 quantitative imaging modalities are displayed on the Selected Host monitor.

Intended Use & Indications for Use:
The ES1 Ultrasound Diagnostic System is intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging of the human body and provides measurements of shear wave speed and tissue stiffness, ultrasound beam attenuation and estimates of speed of sound, in internal structures of the body. This device is intended to be used by trained healthcare professionals, in a healthcare environment.

The ES1 Ultrasound Diagnostic System is indicated for imaging of anatomical structures in the abdomen and measurements of physical properties in the liver and the spleen.

In particular, the ES1 ultrasound diagnostic system is intended to provide:
- Linear distance measurements of anatomical structures,
- Measurement of shear wave speed at selected shear wave frequencies, and estimates of tissue stiffness in the liver and the spleen,
- Estimates of ultrasound attenuation coefficient in the liver at 3.5 MHz,
- Measurement of brightness ratio between structures and in particular between the liver and the kidney,
- Estimates of speed of sound in the liver.

The shear wave speed measurements, ultrasound beam attenuation, elastic properties estimates, brightness ratio may be used as an aid to the diagnosis, monitoring and clinical management of adult and pediatric patients with liver disease.

Substantial Equivalence discussion

The ES1 System operating modalities, principles, and features (B-Mode, 2D-Transient Elastography, estimation of shear wave speed, ultrasound attenuation & speed of sound, and associated combinations as listed in the Diagnostic Ultrasound Indications for Use Table) have been demonstrated to be substantially equivalent to operating modalities, principles, and features of the Predicate & Reference Devices.

Shear wave speed measurement and tissue stiffness estimation are available on the ES1 System with transient elastography (TE) using a mechanical vibration to induce shear waves, thereby technically equivalent to the Predicate Device. The shear wave propagation is tracked by both devices at high pulse repetition frequency, the only difference between them being that tracking is performed by 1D M-Mode with the Predicate Device & 2D B-Mode with ES1 System.
Results of these assessments provide substantially equivalent measurements serving the same intended use as per the Predicate Device, without raising any safety & effectiveness issues.

The ES1 System also provides shear wave speed maps leveraging tracking of shear waves generated by the probe vibrations using 2D imaging, displayed as images of estimated stiffness of tissue. This bidimensional stiffness map extends the effectiveness with respect to the 1D measurement provided by the Predicate Device, and as such similar display to the stiffness map provided by the Reference Device. The ES1 System 2D maps of tissue stiffness derive from different technical characteristics with respect to the Reference Device without raising any issue of safety & effectiveness.

Both the measurement and the map of shear wave speed (and estimated stiffness) are displayed while providing real time B-Mode. This simultaneous display of stiffness and B-Mode is as effective as the Reference Device displaying for the operator the anatomical region where the measurement is performed. The operator can effectively visualize the liver tissue, where the measurement should be made.

The ES1 System provides estimates of ultrasound attenuation in tissue and is substantially equivalent to the Predicate Device which uses CAP (Controlled Attenuation Parameter) technology. The technological differences between methods implemented on the ES1 System and the Predicate Device do not raise issues of safety and effectiveness.
This estimation is performed simultaneously as a real time B-Mode imaging, providing the operator with visualization of the location where the measurement is performed. This visualization of anatomical structures, while measuring the attenuation, contributes to the effectiveness of the method as it is the case in the Reference Device with Att PLUS.

The ES1 System provides estimates of speed of sound in tissue in order to complement information on the tissue as performed on the Reference Device with Ssp PLUS. This measurement does not raise an issue of safety & effectiveness.

The ES1 System operates a single curvilinear array to perform all ultrasound modes, including conventional B-Mode. Although the ES1 System B-Mode imaging has different technological characteristics with respect to the Reference Device, both allow the operator to visualize where measurements are performed and do not raise issues of safety and effectiveness.

The following Table 1 provides supporting elements to the substantial equivalence discussion.

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Table 1 : Substantial Equivalence Comparison

Key points	Predicate Device	Reference Device	New Device
Device Name	FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+ and 630)	AIXPLORER® MACH 30 and AIXPLORER® MACH 20 Ultrasound Diagnostic Systems	ES1 System
Manufactured by	Echosens, France	SuperSonic Imagine, S.A., France	E-Scopics S.A.S., France
510(k) Clearance # and Date	K203273; 03/25/2021	K191007; 10/25/2019	K213102 ;
Classification Name	Ultrasonic pulsed echo imaging system	Ultrasonic pulsed doppler imaging system	Ultrasonic pulsed doppler imaging system
Class	II	II	II
Intended use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body	Diagnostic ultrasound imaging, soft tissue elasticity imaging, fluid flow analysis of the human body.

Indications for use	The FibroScan Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+ and 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. The FibroScan Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+ and 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, and CAP* may be used as an aid in the	The SuperSonic Imagine AIXPLORER® MACH range ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue viscoelasticity imaging, doppler fluid flow analysis of the human body. The SuperSonic Imagine AIXPLORER® MACH 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, Transrectal, Trans-vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac. In addition, the SuperSonic Imagine AIXPLORER® MACH 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,	The ES1 Ultrasound Diagnostic System is intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging of the human body and provides measurements of shear wave speed and tissue stiffness, ultrasound beam attenuation and estimates of speed of sound, in internal structures of the body. This device is intended to be used by trained healthcare professionals, in a healthcare environment. The ES1 Ultrasound Diagnostic System is indicated for imaging and measurements of anatomical structures in the abdomen. In particular, the ES1 ultrasound diagnostic system is intended to provide: - Linear distance measurements of anatomical structures, - Measurement of shear wave speed at selected shear wave frequencies, and estimates of tissue stiffness in the liver and the spleen, - Estimates of ultrasound attenuation coefficient in the liver at 3.5 MHz, - Measurement of brightness ratio between structures and in particular between the liver and the kidney,

	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. *CAP for pediatric patients with liver disease is only available with SmartExam capability on FibroScan Models: 530 Compact, 430 Mini+, and 630.	- Measurements of brightness ratio between liver and kidney, - Visualization of abdominal vascularization, microvascularization and perfusion, - Quantification of abdominal vascularization and perfusion. The shearwave speed, beam attenuation, viscosity 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 and pediatric patients with liver disease.	- Estimates of speed of sound in the liver. The shear wave speed measurements, ultrasound beam attenuation, elastic properties estimates, brightness ratio may be used as an aid to the diagnosis, monitoring and clinical management of adult and pediatric patients with liver disease.
Modes of Operation			
Imaging & quantification modes	A-Mode M-Mode B-Mode (FS630E only for organ localization) Transient Elastography / Shear Wave CAP™	B-Mode (Harmonic, Fundamental) Spatial compounding, Panoramic M-Mode PW CW Color Doppler Amplitude Doppler Microvascular (Angio PL.U.S) Att PLUS SSp PLUS ShearWave Elastography	B-mode Transient Elastography 2D Transient Elastography and Shear Wave Imaging Attenuation measurement Speed of sound measurement

		Contrast-enhanced ultrasound imaging	
Conventional Modes			
B-Mode	B-Mode	B-Mode (Harmonic, Fundamental)	B-Mode
Ultrasound Parameter Estimation and Display			
Ultrasound attenuation	Name: Controlled Attenuation Parameter (CAP) Probe: S+, M+ and XL+ Probes only for liver Technological Characteristics: single beam transmission and reception of ultrasound signals using the monoelement probe with estimation of attenuation at 3,5MHz Range: 100 to 400 dB/m Display: Median, interquartile range (IQR) and IQR/Median ratio (%) Bias range (dB/m @ 3.5 MHz): (6.9%) - (12.2%) Precision range (dB/m @ 3.5 MHz):	Name: Att PLUS Probe: C6-1X probe only for liver and abdomen applications Technological Characteristics: Plane wave ultrasound transmission and reception Wide bandwidth attenuation slope estimation Range: 0.2 dB/cm/MHz to 1.6 dB/cm/MHz Display: Average value	Name: ATT Probe: e.C5-1 probe Technological characteristics: Diverging wave ultrasound transmission and reception Wide bandwidth attenuation slope estimation AND Estimation of attenuation at 3,5Mhz Range: 105 to 350 dB/m 0.3 dB/cm/MHz to 1 dB/cm/MHz Display: Median, interquartile range (IQR) and IQR/Median ratio (%) Bias: (dB/m @ 3.5 MHz): (-22.2%) - (1.4%)

	(0.3%) - (2.1%)		(dB/cm/MHz): (-22.2%) - (1.4%) Precision: (dB/m @ 3.5 MHz): (1.5%) - (4.5%) (dB/cm/MHz): (1.5%) - (4.5%)
Speed of sound	N/A	Name: Speed of sound measurement (Ssp PLUS) Probe: C6-1X probe only for liver and abdomen applications Technological Characteristics: Plane wave ultrasound transmission and reception Wide bandwidth frequency estimation Range: 1450 m/s to 1600 m/S Display: Average value	Name: SOS Probe: e.C5-1 probe Technological Characteristics: Diverging wave ultrasound transmission and reception Wide bandwidth frequency estimation Range: 1450 m/s to 1600 m/s Display: Median, interquartile range (IQR) and IQR/Median ratio (%) Bias: (m/s): (-0.7%) - (0.7%) Precision: (m/s): (0.05%) - (0.3%)
Other Modes Elastography Mode	Name: Vibration-Controlled Transient Elastography (VCTE)	Name: ShearWave Elastography (SWE)	Name: Transient Elastography (2D-TE)

	Type: 1D, quantification without imaging capabilities Shear wave source: External electromechanical vibrator creating a punctual source of vibration Ultrasound tracking: Focused monoelement transmission and reception Range: Liver: Shear wave speed (0.8-5.0 m/s); Stiffness values (2.0-75 kPa) Spleen (FS630E only): Shear wave speed (1.4-5.8 m/s); Stiffness (6.0-100 kPa) Display: Liver: Median value; Interquartile range (IQR); IQR/Median ratio Spleen: Median value; Interquartile range (IQR) Bias: S+ (kPa): (-25.1%) - (7.6%) S+ (m/s): (-13.5%) - (3.6%)	Type: 2D, quantification with imaging capabilities Shear wave source: Supersonic acoustic radiation force Ultrasound tracking: Plane wave transmission and reception Range: Elastography range displayed on the screen (next to color bar) Display: Mean value and Standard Deviation Median/Average values; Interquartile range (IQR)/Standard Deviation values; IQR/Median ratio	Type: 2D, quantification with imaging capabilities Shear wave source: External electromechanical vibrator creating a non-punctual source of vibration, spread along the probe surface Ultrasound tracking: Plane wave transmission and reception Range: Liver: shear wave speed (0.0-5.8); Stiffness values (0.0-100 kPa) Elastography range displayed on the screen (next to color bar) and depends on vibration frequency Display: Median value; Interquartile range (IQR); IQR/Median ratio Bias: (kPa): (-15.7%) - (11.7%) (m/s): (-8.6%) - (5.7%)

	M+ (kPa): (-21.6%) - (1.3%) M+ (m/s): (-11.5%) - (0.7%) XL+ (kPa): (-25.7%) - (2.6%) XL+ (m/s): (-13.9%) - (1.3%) Precision: S+ (kPa): (1.4%) - (4.0%) S+ (m/s): (0.7%) - (2.0%) M+ (kPa): (1.3%) - (3.8%) M+ (m/s): (0.6%) - (1.9%) XL+ (kPa): (0.0%) - (6.3%) XL+ (m/s): (0.0%) - (3.1%)		Precision: (kPa): (0.2%) - (6.0%) (m/s): (0.1%) - (2.9%)
Combined Modes	N/A	Combined modes may include: - B + Color Flow - B + SWE - B + PW - B + WP + Color Flow - B + M - B + SWE + Color Flow - B + CW - B + M + Color Flow - B + Strain + SWE	Combined modes include: - B + 2D-TE or B + SWS - B + ATT - B + SOS - B + Q.US (ATT + SOS)
Product Design			
System Components	- Software - Analog cable hardwired probes - Cart (including computer host)	- Software - Analog cable hardwired probes - Cart (including computer host)	- Software - USB digital hardwired probe - Consumer off-the-shelf (COTS) Selected Host computer
Form factor (Cart based / portable mobile)	Mobile cart-based product with monitor Portable product with monitor	Mobile cart based product with control panel and monitor	Portable product with COTS selected host
Transducers **Ultrasound source**	Piezoelectric ultrasound source	Piezoelectric ultrasound source	Piezoelectric ultrasound source

Transducers **Probe type**	Mono-element ultrasound transducers: M+-probe (3.5 MHz) XL+ probe (2.5 MHz) S+ probe (5 MHz) Multi-elements ultrasound transducer: Convex array: ES-C5-2R60S-3 (3.5 MHz) (FS630E only), OEM MicrUs EXT-1H (#K161968)	Multi-elements ultrasound transducer: Linear arrays: L18-5, L10-2, LV16-5, LH20-6 Convex arrays: C6-1X, C9-2X Microconvex arrays: E12-3, MC12-3 Phased array: P5-1X	Multi-elements ultrasound transducer: Convex array: e.C5-1

Application of Recognized Standards
The ES1 System has been designed & developed to ensure compliance with the following requirements : biocompatibility, acoustic output, cleaning & disinfection, thermal, mechanical, electrical & electromagnetic safety performance taking into account & in accordance with the following standards :

- IEC 60601-1:2005, AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Ed 4.0 : 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-2-37 Ed2.1 2015 : Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- IEC 62127-1 :2007 + amd1:2013 Ultrasonics -- Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz
- IEC 62359 Edition 2.1 2017-09 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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.
- IEC 62366-1 Edition 1.1 2020-06 Medical devices - Part 1: Application of usability engineering to medical devices

Discussion of Performance Data:
The accuracy and precision of the device ultrasound modalities were tested on calibrated phantoms with known reference values.

For B-Mode imaging, the in-vitro performances were good. Contrast resolution enables to distinguish targets having a contrast ratio of +/- 3 dB as compared to the phantom background. The axial resolution of the system is 1 mm, and remains constant over the whole image depth. The lateral resolution ranges from 1 mm to 4 mm depending on the depth of structures. In addition, these performances were shown to not suffer from probe variability. These in vitro assessments were confirmed by the use of the ES1 System on a few subjects in a clinical setting.

The accuracy of quantitative ultrasound modes of the ES1 System was assessed in-vitro by looking at the precision and the bias obtained on a sample of calibrated phantoms. Precision (in %), also known as the within subject coefficient of variation (wCV), was defined as the standard deviation of the independent measurements normalized by the reference value. Bias (in %) was defined as the difference in the mean value measured and the nominal value of the phantom, normalized by the nominal value.

For the estimation of the Speed of Sound, the in-vitro experiments reveal a strong inter-system repeatability on the two considered phantoms. The method demonstrated its robustness against external parameters such as element sensitivity, electronic noise levels of the acquisition chain and small variations of probe geometries on a wide range of speed of sound values. Bias values range in [-0.7 %, 0.7 %] and precision range in [0.05 %, 0.3 %]. The use of Speed of Sound measurements on a few subjects in a clinical setting was also demonstrated to be feasible and safe.

In addition, the accuracy of shear wave speed/stiffness and ultrasound attenuation measurements of the ES1 System and its Predicate Device were compared looking at the precision and the bias obtained with both systems on the same sample of calibrated shear wave speed and ultrasound attenuation phantoms.

For shear wave speed measurements and liver stiffness estimation by the 2D TE method, in-vitro experiments reveal that the stiffness estimation is robust on a wide range of stiffness values and satisfies QIBA technical performance claims. Indeed, the wCV lies in the range [0.1 %, 2.9 %] for the SWS and in the range [0.2 %, 6.0 %] for the corresponding Young's modulus. Bias values lie in the range [-8.6 %, 5.7 %] for the SwS and in the range [-15.7 %, 11.7 %] for Young's modulus. It also reveals a strong inter-system repeatability.
When comparing shear wave speed measurements performed with the ES1 System and its Predicate Device, a high Pearson correlation coefficient of 0.997 was obtained between the 2 systems and methods.

For measurement of the ultrasound attenuation coefficient, the in-vitro performance tests revealed a strong inter-system repeatability. The algorithm is robust against external parameters such as element sensitivity, electronic noise levels of the acquisition chain and small variations of probe geometries. On tested phantoms, the precision lies in the range [1.5 %, 4.5 %], while bias values range in [-22.2% %, 1.4 %]. When compared to its Predicate Device on the same set of calibrated phantoms, ultrasound attenuation estimations with the ES1 System were highly correlated with FibroScan CAP method with a Pearson correlation coefficient of 0.999.

Acoustic Pressure and Intensities of the ultrasound modalities available to the user on the ES1 System were measured. Five transmit patterns (TP) were measured, each of them being used respectively in the five composed imaging modes available on the system. These test results show that the upper-limit values for MI, TI and ISPTA3 are always below the limits recommended in the FDA Guidance for applications other than for ophthalmic use, for ultrasound systems, therefore legitimating the Track 1 approach.

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the ES1 System is not compromised and meet all acceptance criteria, demonstrating that the system is substantially equivalent to the relevant Predicate Device.

Conclusion regarding Substantial Equivalence :
In conclusion, the ES1 System was demonstrated to be substantially equivalent to its Predicate Device K203273, as they have the same intended use, equivalent indications for use, and the technological differences do not raise issues of safety and effectiveness. ES1 System features equivalent to those of the Reference Device K191007 are contributing to ES1 System effectiveness without raising any safety issue as it allows a visualization of the tissue where measurement is performed.

This has been demonstrated via safety & performance testing and comparative data between the ES1 System, its Predicate Device and its Reference Device.

- End of document -