September 26, 2023

E-Scopics
℅ Carine Kessali
Quality Assurance and Regulatory Affairs Manager
931 Chemin de la Bosque d'Antonelle
Aix en Provence, 13090
FRANCE

Re: K232336
Trade/Device Name: ES Series V2
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 31, 2023
Received: September 18, 2023

Dear Carine Kessali:

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,

Marjan Nabili -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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.

Submission Number *(if known)*

K232336

Device Name

ES Series V2

Indications for Use *(Describe)*

The device 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 tissue brightness parameters such as ultrasound beam attenuation and backscattering coefficient, and estimates of speed of sound, in internal structures of the body. The device is intended to be used by trained healthcare professionals, in a healthcare environment.

The device is indicated for imaging of anatomical structures in the abdomen and measurements of physical properties in the liver and the spleen.

In particular, the device 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 tissue brightness parameters in the liver at selected ultrasound frequencies,
- 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 tissue brightness parameters, 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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K232336

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: K232336

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: 20th July 2023

Device Names:

Trade/Proprietary Name:	ES Series V2
Common or Usual Name:	Diagnostic Ultrasound System and Accessories
Device Class	Class II

Classifications:

§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 the predicate device:
Predicate Device: ES1 System (K213102), cleared on 11th of January 2022.

Device description:
E-Scopics' ES Series V2 is an ultraportable ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging and quantitative imaging studies. ES Series V2 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. ES Series V2 is operated from the Selected Host multi-touch screen. ES Series V2 also allows the user to perform measurements, to capture images, and to generate printable reports.

ES Series V2 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, ES Series V2 is designed to measure several quantitative parameters from B Mode imaging: ultrasound tissue brightness parameters such as ultrasound attenuation and backscattering coefficient, speed of sound, and compute ultrasound brightness ratio between 2 regions in the image. The results of ES Series V2 quantitative imaging modalities are displayed on the selected host monitor.

Intended Use & Indications for Use:
The device 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 tissue brightness parameters such as ultrasound beam attenuation and backscattering coefficient, and estimates of speed of sound, in internal structures of the body. The device is intended to be used by trained healthcare professionals, in a healthcare environment.

The device is indicated for imaging of anatomical structures in the abdomen and measurements of physical properties in the liver and the spleen.

In particular, the device 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 tissue brightness parameters in the liver at selected ultrasound frequencies,
- 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 tissue brightness parameters, 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

ES Series V2 operating modalities, principles, and features (B-Mode, 2D-Transient Elastography, estimation of shear wave speed, ultrasound attenuation, backscattering coefficient & 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 Device.

Shear wave speed measurement and tissue stiffness estimation as available on ES Series V2 are equivalent to those available on the Predicate Device, as demonstrated through performance testing , and they serve the same intended use, without raising any safety & effectiveness issues.

ES Series V2 provides estimates of ultrasound tissue brightness, such as ultrasound attenuation and backscattering coefficient in tissue and is substantially equivalent to the Predicate Device as demonstrated by performance testing (verification and validation testing, in vitro performance assessment). The differences in ultrasound sequences and data processing algorithms between methods implemented on ES Series V2 and the Predicate Device do not raise issues of safety and effectiveness.

ES Series V2 provides estimates of speed of sound in tissue, and is substantially equivalent to the Predicate Device as demonstrated by performance testing. The differences in ultrasound sequences and data processing algorithms between methods implemented on ES Series V2 and the Predicate Device do not raise issues of safety and effectiveness.

ES Series V2 operates the same curvilinear array as the Predicate Device to perform all ultrasound modes, including conventional B-Mode. Although ES Series V2 B-Mode imaging has a different post-processing filtering algorithm, ultrasound transmit/receive sequences are identical to the ones implemented in the Predicate Device, without raising issues of safety and effectiveness.

Application of Recognized Standards

ES Series V2 operates the same curvilinear array as the Predicate Device (e.C5-1 Probe), which was designed & developed to ensure compliance with the requirements of standards covering biocompatibility, acoustic output, cleaning & disinfection, thermal, mechanical, electrical & electromagnetic safety performance.

Changes in ES Series V2 as compared to the Predicate Device only reside in ultrasonic sequences updates under track 1, ultrasonic data processing algorithms and

software parts. These limited changes have been designed & developed to ensure compliance with the requirements of standards covering acoustic output and software safety performance:

- 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 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.
- AAMI TIR57:2016 Principles for medical device security - Risk management.

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 below 1 mm, and the lateral resolution of the system is below 2mm.

The accuracy of quantitative ultrasound modes of ES Series V2 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 mean of the independent measurements. Bias (in %) was defined as the difference between the mean value of the independent measurements and the ground truth value of the phantom, normalized by the ground truth value of the phantom.

In addition, the accuracy of shear wave speed/stiffness, speed of sound measurements, ultrasound attenuation measurements and ultrasound basckscatter coefficient measurements of ES Series V2 and the counterpart in its Predicate Device were compared looking at the precision and the bias obtained with both systems on the same sample of calibrated speed of sound, shear wave speed, ultrasound attenuation and ultrasound backscatter coefficient phantoms.

For the estimation of the Speed of Sound, the in-vitro performance tests revealed a strong inter-system repeatability and demonstrated that the algorithm is accurate and robust on a wide range of speed of sound values. Indeed, the wCV lies in the range [0.1%, 0.4%] (CI 95% [0.1%, 2.5%]) while bias values range in [-3.2%, -1.2%] (CI 95% [-4.0%, -0.2%]). When comparing measurements performed with ES Series V2 and

its Predicate Device, a perfect coefficient of determination of 1.000 was obtained between the 2 systems and methods.

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 [0.8%, 3.2%] (CI 95% [0.4%, 20%]) for the shear wave speed and in the range [1.2%, 6.3%] (CI 95% [0.6%, 40%]) for the corresponding Young's modulus. Bias values lie in the range [-15%, 2.2%] (CI 95% [-20%, 9%]) for the SWS and in the range [-27%, 5.6%] (CI 95% [-35%, 18%]) for Young's modulus. It also reveals a strong inter-system repeatability.
When comparing measurements performed with ES Series V2 and its Predicate Device, a high coefficient of determination of 0.99 was obtained between the 2 systems and methods.

For elasticity imaging, the in-vitro performances were good. Average axial and lateral resolution have been measured at 4.3 and 4.0 mm. In addition, the in-vitro performance tests demonstrated that the measurements of the shear wave speed and stiffness within inclusions are accurate and robust on a wide range of values. Indeed, the wCV lies in the range [0.1 %, 0.9 %] (CI 95% [0.1%, 5.3%]) for the shear wave speed and in the range [0.3 %, 1.7 %] (CI 95% [0.1%, 10.6%]) for the corresponding Young moduli while bias values range in [3.8 %, 11.2 %] (CI 95% [3.0%, 13.6%]) for the shear wave speed and in the range [7.5 %, 23.7 %] (CI 95% [5.9%, 28.9%]) for the corresponding Young moduli.
When comparing measurements performed with ES Series V2 and its Predicate Device, a high coefficient of determination of 0.99 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 and demonstrated that the algorithm is accurate and robust on a wide range of attenuation values. Indeed the wCV lies in the range [1.2%, 2.0%] (CI 95% [0.6%, 12.6%]), while bias values range in [-26%, 6.1%] (CI 95% [-28%, 16%]). On the same set of calibrated phantoms, ultrasound attenuation estimations with ES Series V2 were highly correlated with estimations performed with its Predicate Device, with a coefficient of determination correlation of 0.987.

For measurement of the ultrasound backscatter coefficient, the in-vitro performance tests revealed a strong inter-system repeatability and demonstrated that the algorithm is accurate and robust on a wide range of backscatter coefficient values. Indeed the wCV lies in the range [0.8%, 1.7%] (CI 95% [0.3%, 10.8%]), while bias values range in [-13%, -1.1%] (CI 95% [-18%, 0.8%]). On the same set of calibrated phantoms, ultrasound backscatter coefficient estimations with ES Series V2 were highly correlated

with hepatorenal index estimations performed with its Predicate Device, with a coefficient of determination correlation of 0.993.

Acoustic Pressure and Intensities of changed ultrasound modalities available to the user on ES Series V2 were measured: ATT and SOS. 2 transmit patterns (TP) were measured, each of them being used respectively in the three modified 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 ES Series V2 is not compromised and meet all acceptance criteria, demonstrating that the system is substantially equivalent to its Predicate Device.

Conclusions for Clinical Testing:
No clinical testing is necessary to demonstrate substantial equivalence between ES Series V2 and its Predicate Device.

Conclusion regarding Substantial Equivalence:
In conclusion, ES Series V2 was demonstrated to be substantially equivalent to its Predicate Device K213102, as they have the same intended use, equivalent indications for use, and the technological differences do not raise issues of safety and effectiveness.

This has been demonstrated via safety & performance testing between ES Series V2 and its Predicate Device.

Key points	Predicate Device (K213102)	New Device
Device Name	ES1 System	ES Series V2
510(K) owner	E-Scopics S.A.S., France	E-Scopics S.A.S., France
Manufactured by	E-Scopics S.A.S., France	E-Scopics S.A.S., France
Classification Name	Ultrasonic pulsed doppler imaging system	Ultrasonic pulsed doppler imaging system
Class	II	II
Product Code	§892.1550 : Ultrasonic pulsed doppler imaging system (IYN) §892.1560 : Ultrasonic Pulsed Echo Imaging System (IYO) §892.1570 : Diagnostic Ultrasound Transducer (ITX)	§892.1550 : Ultrasonic pulsed doppler imaging system (IYN) §892.1560 : Ultrasonic Pulsed Echo Imaging System (IYO) §892.1570 : Diagnostic Ultrasound Transducer (ITX)
Common or usual name	Diagnostic Ultrasound System and Accessories	Diagnostic Ultrasound System and Accessories
Intended use	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 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. 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:	The device 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 tissue brightness parameters such as ultrasound beam attenuation and backscattering coefficient, and estimates of speed of sound, in internal structures of the body. The device is intended to be used by trained healthcare professionals, in a healthcare environment. The device is indicated for imaging of anatomical structures in the abdomen and measurements of physical properties in the liver and the spleen. In particular, the device is intended to provide:

Key points	Predicate Device (K213102)	New Device
	- 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.	- 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 tissue brightness parameters in the liver at selected ultrasound frequencies, - 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 tissue brightness parameters, 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.
Intended Users	Trained healthcare professionals	Trained healthcare professionals
Imaging & quantification modes	B-mode Transient Elastography 2D Transient Elastography and Shear Wave Imaging Attenuation measurement Speed of sound measurement	B-mode Transient Elastography 2D Transient Elastography and Shear Wave Imaging Attenuation measurement Backscattering coefficient measurement Speed of sound measurement
B-Mode	B-Mode	B-Mode (using equivalent technological characteristics as the Predicate Device as presented in DOC-1797; Theory of Operations - V2 - B-Mode)
Ultrasound attenuation	**Name**: ATT **Probe**: e.C5-1 probe	**Name**: ATT **Probe**: e.C5-1 probe

Key points	Predicate Device (K213102)	New Device
	Technological characteristics: Diverging wave ultrasound transmission and reception Wide bandwidth attenuation slope estimation AND Estimation of attenuation at 3,5Mhz **Range**: 100 to 350 dB/m 0.2 dB/cm/MHz to 1 dB/cm/MHz **Display**: Median, interquartile range (IQR) and IQR/Median ratio (%) (See details in the User Manual) **Bias**: (dB/m @ 3.5 MHz): (-11.6%) - (1.4%) (dB/cm/MHz): (-11.6%) - (1.4%) **Precision**: (dB/m @ 3.5 MHz): (1.5%) - (4.5%) (dB/cm/MHz): (1.5%) - (4.5%)	**Technological characteristics**: Diverging wave ultrasound transmission and reception Estimation of attenuation at 3.5 MHz **Range**: 100 to 350 dB/m @ 3.5 MHz **Display**: Median, interquartile range (IQR) and IQR/Median ratio (%) (See details in the User Manual) **Bias**: (dB/m @ 3.5 MHz): (-26%) - (6.1%) (95% CI): (-28%) - (16%) **Precision**: (dB/m @ 3.5 MHz): (1.2%) - (2.0%) (95% CI): (0.6%) - (12.6%)
Speed of sound	**Name**: SOS **Probe**: e.C5-1 probe **Technological Characteristics**: Diverging wave ultrasound transmission and reception Wide bandwidth frequency estimation **Range**: 1400 m/s to 1650 m/s **Display**: Median, interquartile range (IQR) and IQR/Median ratio (%) (See details in the User Manual)	**Name**: SOS **Probe**: e.C5-1 probe **Technological Characteristics**: Plane wave ultrasound transmission and reception Speed of sound estimation **Range**: 1400 m/s to 1650 m/s **Display**: Median, interquartile range (IQR) and IQR/Median ratio (%) (See details in the User Manual)

Key points	Predicate Device (K213102)	New Device
	Bias: (m/s): (-0.7%) - (0.7%) **Precision**: (m/s): (0.05%) - (0.3%)	**Bias**: (m/s): (-3.2%) - (-1.2%) (95% CI): (-4.0%) - (-0.2%) **Precision**: (m/s): (0.1%) - (0.4%) (95% CI): (0.1%) - (2.5%)
Other Modes Elastography Mode	**Name**: Transient Elastography (2D-TE) **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 (See details in the User Manual) **Bias**: (kPa): (-12.5%) - (28.5%) (m/s): (-6.4%) - (13.2%)	**Name**: Transient Elastography (2D-TE) **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**: Diverging 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 (See details in the User Manual) **Bias:** (kPa): (-27%) - (5.6%) (95% CI): (-35%) - (18%) (m/s): (-15%) - (2.2%) (95% CI): (-20%) - (9.0%)

Key points	Predicate Device (K213102)	New Device
	Precision: (kPa): (0.8%) - (2.7%) (m/s): (0.4%) - (1.4%)	**Precision:** (kPa): (1.2%) - (6.3%) (95% CI): (0.6%) - (40%) (m/s): (0.8%) - (3.2%) (95% CI): (0.4%) - (20%)
Backscattering coefficient	The predicate device ES1 System (K213102) does not provide quantitative BSC measurements but semi-quantitative measurements by means of the hepatorenal index (HRI) (see DOC-1793 Theory of Operations - V2 - Appendices). The backscatter coefficient estimation algorithm as available in the New Device provides a quantitative way to estimate corrected brightness which is similar to HRI from the Predicate Device. Technological characteristics of the two algorithms implemented in the two devices have a high degree of similarity as: - Both devices rely on the same energy-source: pulse-echo US imaging; - They rely on the same electronic boards and the same acoustic head to transmit / receive US data; - The transmit strategy (i.e. 12 Archimedean spiral waves), the transmit waveform are highly similar; Both techniques estimate average brightness ratios between a region of interest i.e the region labeled “L” in the HRI and the region of interest surrounded by yellow borders in the BSC estimation algorithm, and a reference region i.e. the region labeled “K” in the HRI and the region surrounded by yellow borders within the reference phantom for the BSC estimation algorithm.	**Name**: BSC **Probe**: e.C5-1 probe **Technological Characteristics**: Diverging wave ultrasound transmission and reception Estimation of backscatter coefficient in dB/cm-sr at 3 MHz **Range**: -40 dB/cm-sr @ 3 MHz to -20 dB/cm-sr @ 3MHz **Display**: Median, interquartile range (IQR) and IQR/Median ratio (%) **Bias**: (dB/cm-sr @ 3 MHz): (-13%) - (-1.1%) (95% CI): (-18%) - (0.8%) **Precision**: (dB/cm-sr @ 3 MHz): (0.8%) - (1.7%) (95% CI): (0.3 %) - (10.8 %)

Key points	Predicate Device (K213102)	New Device
Combined Modes	Combined modes include: - B + 2D-TE or B + SWS - B + ATT - B + SOS - B + Q.US (ATT + SOS)	Combined modes include: - B + 2D-TE or B + SWS - B + TB (where TB is ATT + BSC) - B + SOS - B + Q.US (ATT + BSC + SOS)
System Components	- Software - USB digital hardwired probe - Consumer off-the-shelf (COTS) Selected Host computer (not provided)	- Software - USB digital hardwired probe - Consumer off-the-shelf (COTS) Selected Host computer (not provided)
Form factor (Cart based / portable mobile)	Portable product with COTS selected host	Portable product with COTS selected host
Acoustic Output Levels (Track 1 & 3)	Track 1	Track 1
Controls	Image Depth Image Gain Mode Select Freeze	Image Depth Image Gain Mode Select Freeze
Power Source	Probe powered via COTS selected host	Probe powered via COTS selected host
Screen	COTS selected host display screen	COTS selected host display screen
Software operating system	COTS selected host equipped with Windows OS	COTS selected host equipped with Windows OS
Transducers Ultrasound source	Piezoelectric ultrasound source	Piezoelectric ultrasound source
Transducers Probe type	Multi-elements ultrasound transducer: Convex array: e.C5-1	Multi-elements ultrasound transducer: Convex array: e.C5-1

Key points	Predicate Device (K213102)	New Device
Cleaning / Disinfecting methods & materials	Methods: Soft cloth wiping Soaking prohibited Materials: Isopropyl alcohol / Alkylamine Quaternary amonium Chlorine dioxide	Methods: Soft cloth wiping Soaking prohibited Materials: Isopropyl alcohol / Alkylamine Quaternary amonium Chlorine dioxide
Report	Yes, available in pdf	Yes, available in pdf
Target Patient Population (if applicable)	General purpose imaging system	General purpose imaging system
Patient Population exclusion (if applicable)	- Patients with active implants such as pacemakers, defibrillators, pumps, etc. - Wounds	- Patients with active implants such as pacemakers, defibrillators, pumps, etc. - Wounds