April 28th, 2026

E-Scopics
Aurelie Gruener
QARA Director
235 Rue Léon Foucault
Aix-En-Provence, 13290
FRANCE

Re: K260589
Trade/Device Name: ES-Series
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 20, 2026
Received: February 20, 2026

Dear Aurelie Gruener:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Digitally signed by Michael D. O'hara -S
Date: 2026.04.29 15:53:48 -04'00' For

Yanna Kang, Ph.D.
Assistant Director
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260589

Please provide the device trade name(s).

ES-Series

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K260589

510(k) Summary

Prepared on: 2026-03-31

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	E-Scopics
Applicant Address	235 Rue Léon Foucault Aix-en-Provence 13290 France
Applicant Contact Telephone	0033664366992
Applicant Contact	Mrs. AURELIE GRUENER
Applicant Contact Email	aurelie.gruener@e-scopics.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ES-Series
Common Name	Ultrasonic pulsed doppler imaging system
Classification Name	System, Imaging, Pulsed Doppler, Ultrasonic
Regulation Number	892.1550
Product Code(s)	IYN, IYO, ITX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232336	Proprietary name: Hepatoscope; filed under ES Series V2 in K232336	IYN

Device Description Summary

21 CFR 807.92(a)(4)

ES Series is an ultraportable ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging and quantitative imaging studies. ES Series consists of a Software App (running on a consumer off-the-shelf Selected Host) and an accessory probe. The system produces images and quantifications, which are displayed on the monitor of the Selected Host. ES Series is operated from the Selected Host and allows the user to perform measurements, to capture images, and to generate printable reports.

The product is an ultraportable software-based ultrasound imaging device that is composed of an external transabdominal ultrasound probe equipped with a mechanical vibrator to produce shear waves in tissue, and connected to an off-the-shelf software host via a standard USB-C cable. The system software is operated by the host and is responsible for controlling the probe, for processing ultrasound data, and for exam management. Operating functionalities performed by the digital probe are limited to the transmission, the reception and the digitization of ultrasound signals, before transferring them to the processing host via the USB-C cable. This processing host runs the Hepatoscope App, which ensures the following functions:

- Control of the ultrasound transmit/receive sequences by the probe;
- Processing of the raw ultrasound data that are received from the probe;
- Display of the reconstructed imaging information (images, quantitative parameters…)

This ultrasound imaging device allows the operator to acquire information coming from quantitative imaging modalities such as elastography, tissue brightness parameters, speed of sound. This can be done under real-time 2D imaging guidance.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Intended Use and Indications for Use remain identical to the predicate.

Technological Comparison

21 CFR 807.92(a)(6)

ES Series has the same technological characteristics as the Predicate Device: same operating modalities, principles, features (B-mode, 2D-Transient Elastography, Shear Wave Speed estimation, attenuation coefficient, backscattering coefficient, and Speed of Sound), and associated combinations of modes.

- Spleen stiffness workflow: The signal processing and ultrasound sequence have been refined to target higher stiffness values as in the spleen. Performance data demonstrate that these updates are substantially equivalent to the Predicate Device and do not raise new questions of safety or effectiveness.

- Support of macOS platforms: The addition of the macOS operating system as a compatible host, alongside the existing Windows operating system, has been validated by performance data. This expansion is considered substantially equivalent to the Predicate Device and does not raise different questions of safety and effectiveness.

- Addition of connectivity: The implementation of connectivity to EHR using HL7 FHIR standard does not raise different questions of safety and effectiveness to the Predicate Device as demonstrated by performance data.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

A series of non-clinical tests were performed to ensure that improvment of technological characteristics of ES Series do not affect the safety or effectiveness of the device. The following performance data were collected and analyzed:
- Electrical safety testing were conducted on the ES Series device. The device complies with the IEC 60601-2-37.
- Bench testing were conducted on calibrated phantoms to demonstrate the accuracy of the signal processing and ultrasound sequence refinements for spleen stiffness.
- Software Verification and Validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device was considered as Basic Documentatio Level.

Clinical testing was not deemed necessary to demonstrate substantial equivalence.

Conclusion:
ES Series demonstrated to be substantially equivalent to its Predicate Device as they have the same intended use and indications for use, and the technological differences do not raise issues of safety and effectiveness.
This has been demonstrated via safety & performance testing between the ES Series and its Predicate Device.