April 6, 2026

Esaote S.p.A.
Vanessa Ronconi
Regulatory Affairs Leader
via Enrico Melen 77
Genoa, GE 16152
Italy

Re: K253288
Trade/Device Name: 6450 Ultrasound System (MyLabE80); 6450 Ultrasound System (MyLabE85)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: September 26, 2025
Received: September 29, 2025

Dear Vanessa Ronconi:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.04.06 14:59:51 -04'00'

For

Yanna Kang
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.	K253288

Please provide the device trade name(s).

6450 Ultrasound System (MyLabE80);
6450 Ultrasound System (MyLabE85)

Please provide your Indications for Use below.

The multifunctional ultrasound scanner is used to collect, display and analyze ultrasound images during ultrasound imaging procedures in combination with supported echographic probes.

Main application:	Districts:	Invasive access:
Cardiac	Cardiac Adult, Cardiac Pediatric	Transesophageal
Vascular	Neonatal, Adult Cephalic, Vascular	Not applicable
General Imaging	Abdominal, Breast, Musculoskeletal, Neonatal, Pediatric, Small Organs (Testicles), Thyroid, Urological	Intraoperative (Abdominal), Laparoscopic, Transrectal
Women Health	OB/Fetal, Gynecology	Transrectal, Transvaginal

Virtual Navigator option supports a radiological clinical ultrasound examination (first modality) by providing additional image information from a second imaging modality. As second imaging modality it is intended any image coming from CT, MR, US, PET, XA and NM.
The second modality provides additional security in assessing the morphology of the real time ultrasound image.

The primary modes of operation are: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler (both Pulsed Wave (PW) and Continuous Wave (CW)), Color Flow Mapping (CFM), Power Doppler, Tissue Velocity Mapping (TVM), Combined modes, Elastosonography, 3D/4D and CnTI.
The ultrasound scanner is suitable to be installed in professional healthcare facility environment and is designed for ultrasound practitioners.

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

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

510(k) #: K253288

510(k) Summary

Prepared on: 2026-04-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Esaote S.p.A.
Applicant Address	via Enrico Melen 77 Genoa GE 16152 Italy
Applicant Contact Telephone	+39 334 3432808
Applicant Contact	Ms. Vanessa Ronconi
Applicant Contact Email	fda@esaote.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	6450 Ultrasound System (MyLabE80); 6450 Ultrasound System (MyLabE85)
Common Name	Ultrasonic pulsed doppler imaging system
Classification Name	System, Imaging, Pulsed Doppler, Ultrasonic
Regulation Number	892.1550
Product Code(s)	IYN, IYO (892.1560), ITX (892.1570), QIH (892.2050)

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241671	6450 Ultrasound System (MyLabE80); 6450 Ultrasound System (MyLabE85)	IYN
K243253	6600 Ultrasound System (MyLabA50); 6600 Ultrasound System (MyLabA70)	IYN

Device Description Summary

21 CFR 807.92(a)(4)

6450 Ultrasound System is a general-purpose diagnostic ultrasound system, based on a mainframe platform that can be easily moved thanks to four swivelling wheels.
6450 Ultrasound System consists of a control panel assembly with LCD monitor and a console with the device electronics and connectors, housed in an ergonomic cart designed to be both highly mobile and adjustable for a range of users and operating conditions.
6450 Ultrasound System uses the physical properties of the ultrasound (i.e. sound waves with frequency above 20 kHz and that are not audible to the human ear) for the visualization of deep structures of the body by recording the reflections or echoes of ultrasonic pulses directed into the tissues and of the Doppler effect, i.e. the frequency-shifted ultrasound reflections produced by moving targets (usually red blood cells) in the bloodstream, to determine both direction and velocity of blood flow in the target organs.
The primary modes of operation are: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler (both PW and CW), Color Flow Mapping (CFM), Power Doppler, Tissue Velocity Mapping (TVM), Combined modes. 6450 Ultrasound System also manages Elastosonography (ElaXto, QElaXto, QElaXto 2D), 3D/4D and CnTI.

Several types of probes are used to cover different needs in terms of geometrical shape and frequency range.
6450 Ultrasound System can drive Phased Array, Convex Array, Linear Array, Doppler probes and Volumetric probes (Bi-Scan probes).
The control panel is equipped with a pull-out Qwerty alphanumeric keyboard that allows data entry. The touchscreen has an emulation of the Qwerty keyboard that allows data entry and has additional controls and mode-depending keys, integrated in the touchscreen.
6450 Ultrasound System is equipped with wireless capability.

6450 Ultrasound System is available on the market in two models with the following commercial names: MyLabE80, MyLabE85.
The difference between MyLabE80 and MyLabE85 models is only in the licenses configuration.

For both models, there is the ETC (Easy To Clean) version, having a keyboard with special controls and material, compatible with disinfection procedures.

6450 Ultrasound System, defined herein, introduces the following new feature:
• UroFusion (including an AI-algorithm): a dedicated software feature designed to support a radiological clinical ultrasound examination (first modality) of the prostate by providing additional image information from a second imaging modality. UroFusion represents an improvement of the previously cleared Virtual Navigator feature, specific for the urology application.

In addition, the following features, previously cleared under K243253, are now being made available on the 6450 Ultrasound System:
• AutoCM (available with PX 1-5 probe)
• AutoOB (available with C 1-8, C 2-9 and SB2C41 probes)
• XStrain RV (available with PX 1-5 probe)

6450 Ultrasound System employs the same fundamental technological characteristics as its predicate device cleared under K241671.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The multifunctional ultrasound scanner is used to collect, display and analyze ultrasound images during ultrasound imaging procedures in combination with supported echographic probes.

Main application:	Districts:	Invasive access:
Cardiac	Cardiac Adult, Cardiac Pediatric	Transesophageal
Vascular	Neonatal, Adult Cephalic, Vascular	Not applicable
General Imaging	Abdominal, Breast, Musculoskeletal, Neonatal, Pediatric, Small Organs (Testicles), Thyroid, Urological	Intraoperative (Abdominal), Laparoscopic, Transrectal
Women Health	OB/Fetal, Gynecology	Transrectal, Transvaginal

Virtual Navigator option supports a radiological clinical ultrasound examination (first modality) by providing additional image information from a second imaging modality. As second imaging modality it is intended any image coming from CT, MR, US, PET, XA and NM.
The second modality provides additional security in assessing the morphology of the real time ultrasound image.

The primary modes of operation are: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler (both Pulsed Wave (PW) and Continuous Wave (CW)), Color Flow Mapping (CFM), Power Doppler, Tissue Velocity Mapping (TVM), Combined modes, Elastosonography, 3D/4D and CnTI.
The ultrasound scanner is suitable to be installed in professional healthcare facility environment and is designed for ultrasound practitioners.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the 6450 Ultrasound System are the same as those of predicate device, cleared via K241671.

Technological Comparison

21 CFR 807.92(a)(6)

The new version of Esaote 6450 Ultrasound System is substantially equivalent to the predicate device 6450 Ultrasound System (cleared under K241671) with regard to intended use, imaging capabilities, technological characteristics, and safety and effectiveness.

• The systems are all intended for diagnostic ultrasound imaging.
• The proposed 6450 Ultrasound System and the predicate device have the same clinical use.
• The proposed 6450 Ultrasound System and the predicate device have the same imaging modes and modes of operation.
• The proposed 6450 Ultrasound System and the predicate device have the same capability in terms of performing measurements,

capturing digital images, reviewing and reporting studies.
• The proposed 6450 Ultrasound System and the predicate device have been designed in compliance with approved electrical and physical safety standards.
• The proposed 6450 Ultrasound System is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
• The proposed 6450 Ultrasound System has acoustic power levels which are below the applicable FDA limits.
• The proposed 6450 Ultrasound System implements Microsoft Windows 10 operating system, exactly like the predicate device.
• The proposed 6450 Ultrasound System and the predicate device manage the same probes.
• The proposed 6450 Ultrasound System introduces the new feature UroFusion (including an AI-algorithm), which represents an improvement of the previously cleared Virtual Navigator feature already available on the predicate device, specific for the urology application.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Summary of Non-Clinical Tests
The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform with applicable medical device safety standards.
6450 Ultrasound System complies with the following standards:
- ANSI/AAMI ES60601-1:2005/AMD2:2021, Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance
- ANSI/AAMI/IEC 60601-1-2:2014 + AMD1:2021, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010+A1:2013 + A2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-37:2007 + A1:2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (Revision 3)
- NEMA UD 3-2004 (R2009), Standard For Real-Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (Revision 2)

AI Summary of Testing: UroFusion including an AI algorithm for prostate contouring

Description:
The AI algorithm for prostate contouring is designed to support clinicians during fusion imaging examinations of the prostate by automatically segmenting the prostate gland on both MR and ultrasound images. It is available only into the "Urology" application within the UroFusion tool on the ultrasound system. The algorithm is based on a U-Net architecture to automatically segment the prostate and is designed exclusively for use on prostate glands. The final review and approval of the segmentation output remain under the responsibility of the clinician.
Performance testing comparing the AI-generated contours with manually defined contours has demonstrated that the algorithm meets the established performance criteria.

Acceptance criteria defined to evaluate the performance of the AI algorithm for prostate contouring:
- DICE Volume ≥ 0.7
- Computational Time < 15 seconds
To ensure statistical robustness, a 95% confidence interval is computed for the mean DICE value and time.
All test results are in line with the acceptance criteria.

Demographics:
Dataset employed to develop, test and validate the algorithm includes prostate images from male patients aged 20 to 80 years, from U.S. and European populations.

Clinical subgroups and confounders present in the dataset:
No clear and established clinical guidelines are currently available regarding prostate morphology and its related categories except for age, which is associated with the physiological enlargement of the gland.
The AI algorithm performance was evaluated across the following variables to confirm consistency and generalizability of the results:
- Age
- Prostate volume
- PI-RADS score
- Body Mass Index (BMI)
Subgroup analyses were also performed based on the MRI and ultrasound systems manufacturers to ensure that model performance is not biased by imaging hardware.
The dataset includes individuals from both U.S. and European populations.

Race and ethnicity were not used as subgroup variables, as they are not considered clinically relevant to prostate imaging outcomes.
The algorithm met all predefined performance criteria across all evaluated subgroups.

Limitations:
The AI algorithm is applicable only to T2-weighted MRI sequences and B-Mode ultrasound images, provided that the entire volume of the patient's prostate has been acquired.

MRI Compatibility:
The AI algorithm was validated using prostate MRI data acquired from the following MRI systems operating at 1.5 Tesla:
- Siemens MAGNETOM
- GE SIGNA
- Toshiba MEC
- Philips Ingenia Ambition S and Achieva

Compatibility with other MRI systems, models, or magnetic field strengths has not been established.

"Truthing" process:
Data have been acquired in a diagnostic process during MRI targeted biopsy procedures, many of which included image fusion with MRI targets. Patients received a 3D transrectal ultrasound scan, after which registration (e.g. "fusion") was performed between real-time ultrasound and preoperative MRI. The procedure is conducted under the supervision of a radiologist and a urologist, who ensure that the labelling required for the examination is certified by the actual execution of the procedure. This clinical process ensures the quality and reliability of the data used to perform biopsy.

Ensuring independence of test data from training data:
The AI algorithm was trained on:
- 1016 series from 841 patients for MR dataset.
- 128 volumes from 128 patients for U/S dataset.

The AI algorithm was tested/validated on:
- 150 series from 150 patients for MR dataset.
- 1727 volumes from 1172 patients for U/S dataset.

The datasets used for training and tuning are independent at the patient level. Patients included in the training dataset were explicitly excluded from the tuning dataset, and vice versa.
The datasets used for testing and validation are also fully independent from those used for training and tuning. These datasets were acquired in a subsequent phase, after the algorithm development, from different clinical centers or from publicly available sources. Notably, for the U/S test dataset—which was derived from the same public database used for MR training/tuning data—independence is ensured through the use of a different imaging modality (U/S for testing vs. MR for training/tuning).
This approach ensures that all data used for testing and validation are clinically independent from the data used during algorithm development.

Summary of Clinical Tests
The proposed device did not require clinical studies to support substantial equivalence.

Conclusion
The 6450 Ultrasound System is substantially equivalent to its predicate device currently marketed and conform to applicable medical device safety and performance standards.