May 16, 2025

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

Re: K241671
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: April 22, 2025
Received: May 7, 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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: 2025.05.16 13:30:06 -04'00'

For

Julie Sullivan, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241671

Device Name

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

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K241671

510(k) Summary

Prepared on: 2025-05-15

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	+39 345 6141201
Applicant Contact	Mr. Piet De Jong
Applicant Contact Email	fda@esaote.com
Correspondent Name	Esaote S.p.A.
Correspondent Address	via Enrico Melen 77 Genoa GE 16152 Italy
Correspondent Contact Telephone	+39 334 3432808
Correspondent Contact	Ms. Vanessa Ronconi
Correspondent 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
K192157	6450 MyLabX8	IYN
K230179	6440 MyLabX90	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 use 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 will be 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 new features and accessories listed below:
1. XStrain LA: XStrain allows clinicians to quantify endocardial velocities of contraction and relaxation and local deformation of the heart (Strain/Strain rate). XStrain LA is an advanced processing package for the Left Atrium analysis.
2. New probe: IHX 6-25

6450 Ultrasound System employs the same fundamental technological characteristics as its predicate device cleared via K192157.

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 K192157.

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

via K192157) 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 implement Microsoft Windows 10 operating system, exactly like the predicate device.
• The proposed 6450 Ultrasound System has included new software features, that are all improvement/extension of previous features/ functionalities already available either on the predicate device or the reference device (6440 MyLabX90 Ultrasound System cleared via K230179):
  - XStrain LA: extension of the XStrain feature available on predicate device.
• Additional Easy-to-clean (ETC) control panel configuration available, not affecting clinical performance and safety of the subject device.
• The following probe is newly added in the present submission: IHX 6-25. IHX 6-25 is equivalent to the IH 6-18, cleared via K192157. Biocompatibility evaluation and image performance tests have been conducted for the new probe.
• 2CWS and 5CWS are the new names for the old cleared probes, respectively S2MCW and S5MCW, both cleared via K192157.

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/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance
– IEC 60601-1-2:2014 + AMD1:2020 (Ed. 4.1), 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, 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)

Summary of Testing, Strain Left Atrium (LA):

Description:
Strain functionality Left atrium (LA) with manual segmentation.
Medical Imaging, (that is part of Esaote S.p.A. group), using TomTec AutoSTRAIN (part of TomTec Arena TTA2 LOT 42.0) as prior reference.
The validation is performed as follows:
1. A strain analysis is done for one complete heart cycle on each of the image runs described above, using the us_cardiac module. The initial contour and corresponding frame index are equal to the ones used during the creation of the TomTec references, to ensure a meaningful comparison.
2. The LASr, LAScd and LASct results for each image run are compared to the corresponding TomTec reference.

The ICC, Intraclass Correlation Coefficient result is valid for all Left Atrium Strain indexes (LASr, LAScd and LASct):
LASr = 0.84
LAScd = 0,76
LASct = 0,74

Demographics:
Patients with age ≥ 18 years.

Clinical subgroups and confounders present in the dataset:
Patients with a variety of left ventricular functional states and subjects with normal cardiac function

including documented myocardial infarction within maximum two years before the study and patients with suspected or documented coronary heart disease.

Equipments:
Esaote MyLabAlpha Ultrasounds system
GE Vivid E9 and Vivid E95 Ultrasounds systems
Esaote 6450 MyLabX8 ultrasound system
GE Vivid E9 ultrasound system

"Truthing" process:
For the clinical evaluation five batches of image data are used.
A batch of images was acquired using an Esaote MyLab Alpha system in the context of a multi-vendor strain comparison study (Farsalinos, Daraban, Ünlü, & Thomas, 2015).
The second batch of images was also acquired using an Esaote MyLab Alpha system in the context of multi-vendor strain comparison study (Mirea, et al., 2018).
The third batch of images was acquired at the cardiology department of the Amsterdam Medical Center by experienced cardiographers
The last batch of images was acquired at the cardiology department of Auxologico hospital Milan by experiences cardiographers
The study was approved by the ethical commission of the University Hospital Leuven

LA strain validation—comparison against reference software images

ETC Easy To Clean Keyboard
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The usability of new Easy To clean keyboard is included in IEC60601 test report, inclused in the eStar dossier.
All the IEC requirements have been satisfied.

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.