June 18, 2025

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

Re: K243253
Trade/Device Name: 6600 Ultrasound System (MyLabA50); 6600 Ultrasound System (MyLabA70)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: May 23, 2025
Received: May 23, 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,

YANNA S. KANG -S

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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)*

K243253

Device Name

6600 Ultrasound System (MyLabA50);
6600 Ultrasound System (MyLabA70)

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

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.

510(k) #: K243253

510(k) Summary

Prepared on: 2025-05-23

K243253

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Ms. Vanessa Ronconi
Correspondent Contact Email	fda@esaote.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	6600 Ultrasound System (MyLabA50); 6600 Ultrasound System (MyLabA70)
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
K230179	6440 MyLabX90	IYN

Device Description Summary

21 CFR 807.92(a)(4)

6600 Ultrasound System is a general-purpose diagnostic ultrasound system, based on a mainframe platform that can be easily moved thanks to four swivelling wheels.
6600 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.
6600 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. 6600 Ultrasound System also manages Elastosonography, 3D/4D and CnTI.

Several types of probes are used to cover different needs in terms of geometrical shape and frequency range.
6600 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.
6600 Ultrasound System is equipped with wireless capability.

6600 Ultrasound System will be available on the market in two models with the following commercial names: MyLabA50, MyLabA70.
The difference between MyLabA50 and MyLabA70 models is only in the licenses configuration.

6600 Ultrasound System, defined herein, introduces new features and accessories listed below:
1. AutoOB: AutoOB (Automatic Obstetric Biometric Measurement) is a tool based on A.I. algorithms that supports the clinician in performing the Obstetric Biometric Measurements during an Obstetric ultrasound examination.
2. AutoCM: AutoCM (Automatic Cardiac Measurement), is a tool based on A.I. algorithm that supports the clinician in performing the Cardiac Measurements during a Cardiac ultrasound examination.
3. XStrain RV: XStrain allows clinicians to quantify endocardial velocities of contraction and relaxation and local deformation of the heart (Strain/Strain rate). XStrain RV is an advanced processing package for the Right Ventricle analysis.
4. New probes: C 1-8E, L 3-15E and P 1-5E, available for MyLabA50 model.
5. New probes: C 1-8A and P 1-5A, available for MyLabA70 model.

6600 Ultrasound System employs the same fundamental technological characteristics as its predicate device cleared via K230179.

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

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 6600 Ultrasound System are the same as those of predicate device, cleared via K230179.

Technological Comparison

21 CFR 807.92(a)(6)

6600 Ultrasound System is substantially equivalent to the predicate device (cleared via K230179) with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

• The systems are all intended for diagnostic ultrasound imaging.
• The proposed 6600 Ultrasound System and the predicate device have the same clinical use.
• The proposed 6600 Ultrasound System and the predicate device have the same imaging modes and modes of operation.

• The proposed 6600 Ultrasound System and the predicate device have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
• The proposed 6600 Ultrasound System and the predicate device have been designed in compliance with approved electrical and physical safety standards.
• The proposed 6600 Ultrasound System is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
• The proposed 6600 Ultrasound System has acoustic power levels which are below the applicable FDA limits.
• The proposed 6600 Ultrasound System implement Microsoft Windows 10 operating system, exactly like the predicate device.
• The proposed 6600 Ultrasound System has included new Software features: AutoOB (AI-powered), AutoCM (AI-powered), XStrain RV. All these new features are improvement of previous features/functionalities already available on the predicate device:
- AutoOB (AI-powered): improvement of the existing AutoOB feature;
- AutoCM (AI-powered): improvement of the existing manual cardiac measurement function;
- XStrain RV: extension of the existing XStrain feature.
• Additional Easy-to-clean (ETC) control panel configuration available, not affecting clinical performance and safety of the subject device.
• The following probes are newly added in the present submission: C 1-8E, C 1-8A, L 3-15E, P 1-5E, P 1-5A. C 1-8E and C 1-8A are both equivalent to the cleared C 1-8; L 3-15E is equivalent to the cleared LX 3-15; P 1-5E and P 1-5A are both equivalent to the cleared P 1-5. Biocompatibility evaluation and image performance tests have been conducted for the new probes.

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.
6600 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)

AI Summary of Testing: Automatic Obstetric Biometric Measurements (AutoOB) feature AI-powered

AutoOB tool is based on two different A.I. algorithms:
- An algorithm for the classification of the acquired scan plane
- An algorithm for the segmentation and measurement
The acceptance criteria are aimed to demonstrate the statistical equivalence between the automated and manual scan plane classification and between the automated and manual biometric measures results.
Criteria to establish the final positive or negative outcome of the validation of the scan plane classification algorithm:
- Head TT/TV plane: success rate > 90%
- Head TCD plane: success rate > 90%
- Abdomen plane: success rate > 90%
- Bones: success rate > 90%
- Sagittal CRL: success rate >90%
- Sagittal NT: success rate > 85%
Criteria to establish the final positive or negative outcome of the validation of the automatic measure algorithm:
- Head Circumference (HC): Success Rate >= 90%
- Biparietal Diameter (BPD): Success Rate >= 90%
- Abdominal Circumference (AC): Success Rate >= 90%
- Femur Length (FL): Success Rate>=75%
- Crown Rump Length (CRL): Success Rate>=75%
- Transverse cerebellar diameter (TCD): Success Rate >= 90%
- Humerus Length (HL): Success Rate>=90%
- Ulna Length (UL): Success Rate>=90%
- Tibia Length (TL): Success Rate>= 90%
- T-Test acceptance criteria: Automatic and manual measures are statistically equivalent (not rejecting the null hypothesis) with 95% confidence level.

All test results are in line with the acceptance criteria.

Demographics
Both Training and Test Datasets are based on female, pregnant, Caucasian patients and report US images of obstetric examinations performed during all gestational trimesters.

Clinical subgroups and confounders present in the dataset
No discrimination on specific pathologies has been considered since the tool is aimed at speeding up the measurement tracing workflow in Ob-fetal examinations and the measures extracted by the algorithm are not depending on patient pathology.

Equipment
The acquisition equipment is the Ultrasound system Esaote MyLabX8 with Esaote convex transducers. All ultrasound scanners of the Esaote MyLab family share the same software and image format; therefore, applicability to all Esaote Ultrasound systems is guaranteed.
Images have been saved during the examinations and measurements have been carried out with standard measure tools available on Esaote MyLabX8 US equipment.
Data annotation includes information about:
- structure patterns visible in every scan plane and proper biometric measurements for the acquired plane, for Scan plane classification algorithm;
- gestational age and acquired scan plane, for Automatic measure algorithm.

"Truthing" process
The consensus of expert panel has been used as ground truth for both training and test datasets.
The expert panel consists of clinicians specialized in Radiology with 30 and 24 years of experience in Ob-fetal ultrasound imaging. Each contributed to the annotation then reviewed the annotations of the other. A consensus reading was done whereby the two radiologist discussed if they agreed on or not.
The delivered data were archived and delivered in 2 separated repository and confirmed no overlap between the training and test datasets.

Ensuring independence of test data from training data
The Scan plane classification algorithm was trained on 25597 images (training dataset) and tested on 265 images (test dataset).
The Automatic measure algorithm was trained on 11698 images (training dataset) and tested on 521 images (test dataset).
There is no overlap between training datasets and testing datasets.

AI Summary of Testing: Automatic Cardiac Measurements (AutoCM) feature AI-powered

AutoCM tool is based on an algorithm for the segmentation and measurement.
The acceptance criteria are aimed to demonstrate the statistical equivalence between the automated and manual biometric measures results.
Criteria to establish the final positive or negative outcome of the validation:
- IVS: Success Rate > 80%
- LVID: Success Rate > 90%
- LVPW: Success Rate > 70%
- T-Test acceptance criteria: Automatic and manual measures are statistically equivalent (not rejecting the null hypothesis) with 95% confidence level.
All test results are in line with the acceptance criteria.

Demographics
Both Training and Test Datasets are based on both female and male Caucasian adult patients and report US images of cardiac examinations.

Clinical subgroups and confounders present in the dataset
No discrimination on specific pathologies has been considered since the tool is aimed at speeding up the measurement tracing workflow in cardiac exams and the measures extracted by the algorithm are not depending on patient pathology.

Equipment
The acquisition equipment is the Ultrasound system Esaote MyLabX8 with Esaote phased array transducers. All ultrasound scanners of the Esaote MyLab family share the same software and image format; therefore, applicability to all Esaote Ultrasound systems is guaranteed.
Images have been saved during the examinations and measurements have been carried out with standard measure tools available on Esaote MyLabX8 US equipment.
Data annotation includes information about IVS, LVID and LVPW measures.

"Truthing" process
The consensus of expert panel has been used as ground truth for both training and test datasets.
The expert panel for training dataset consists of clinicians specialized in Cardiology with 34 and 24 years of experience in cardiac ultrasound imaging. Each contributed to the annotation then reviewed the annotations of the other. A consensus reading was done whereby the two cardiologists discussed if they agreed on or not.
The test dataset has been acquired and labelled in a different medical center by a clinician specialized in Cardiology with 36 years of experience.

Ensuring independence of test data from training data
The algorithm was trained on 2011 images (training dataset) and tested on 100 images (test dataset).
There is no overlap between training datasets and testing datasets.

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

Conclusion
The 6600 Ultrasound System is substantially equivalent to its predicate device currently marketed and conform to applicable medical device safety and performance standards.