November 25, 2025

Esaote S.p.A
Antonia Perrella
Regulatory Affairs Leader
Via Enrico Melen 77
Genova, 16152
Italy

Re: K253310
Trade/Device Name: 7600 Ultrasound System (MyLabC25);
7600 Ultrasound System (MyLabC30)
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 29, 2025
Received: November 3, 2025

Dear Antonia Perrella:

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,

Daniel M. Krainak, 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.	K253310

Please provide the device trade name(s).

7600 Ultrasound System (MyLabC25);
7600 Ultrasound System (MyLabC30)

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 applications
- Cardiac
  Districts: Cardiac Adult, Cardiac Pediatric (including newborns)
  Invasive access: Transesophageal
- Vascular
  Districts: Neonatal, Adult Cephalic, Vascular
  Invasive access: Not applicable
- General Imaging
  Districts: Abdominal, Musculo-skeletal, Neonatal, Pediatric, Small Organ (Testicles, Breast, Thyroid), Urologic
  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 PW and CW), Color Flow Mapping (CFM), Power Doppler, Tissue Velocity Mapping (TVM), Combined modes, Elastosonography, 3D/4D and CnTI.

The ultrasound scanner is suitable for use in health institutions and is designed for ultrasound practitioners.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-11-25

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	+39 380 2346712
Applicant Contact	Ms. Antonia Perrella
Applicant Contact Email	fda@esaote.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	7600 Ultrasound System (MyLabC25); 7600 Ultrasound System (MyLabC30)
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
K243253	6600 Ultrasound System (MyLabA50); 6600 Ultrasound System (MyLabA70)	IYN
K241671	6450 Ultrasound System (MyLabE80); 6450 Ultrasound System (MyLabE85)	IYN

Device Description Summary

21 CFR 807.92(a)(4)

7600 Ultrasound System is a portable based ultrasound device used to perform diagnostic general ultrasound studies.
7600 Ultrasound System is equipped with two LCD Color Displays. The first LCD Color Display is the main output device used to display the acquisition image, the acquisition configuration and the exam results. The second LCD is provided with Touch panel and is used as a flexible input control device because its easy configurability.
The device 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. 7600 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.
7600 Ultrasound System can drive Phased array, Convex array, Linear array, Doppler probes and Volumetric probes (Bi-Scan probes).
7600 Ultrasound System is equipped with wireless capability.
7600 Ultrasound System will be available on the market in two models with the following commercial names: MyLabC25, MyLabC30. The difference between MyLabC25 and MyLabC30 models is only in the licenses configuration.
7600 Ultrasound System, defined herein, is a new portable version of the cart-based 6600 Ultrasound System previously cleared under K243253.

The proposed 7600 Ultrasound System includes a new software version that combines features FDA-cleared and already available in the predicate and reference devices (K243253 and K241671). No new functionalities have been introduced in the current software release compared to the version previously cleared.
7600 Ultrasound System employs the same fundamental technological characteristics as its predicate device cleared via K243253.

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 applications
- Cardiac
  Districts: Cardiac Adult, Cardiac Pediatric (including newborns)
  Invasive access: Transesophageal
- Vascular
  Districts: Neonatal, Adult Cephalic, Vascular
  Invasive access: Not applicable
- General Imaging
  Districts: Abdominal, Musculo-skeletal, Neonatal, Pediatric, Small Organ (Testicles, Breast, Thyroid), Urologic
  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 PW and CW), Color Flow Mapping (CFM), Power Doppler, Tissue Velocity Mapping (TVM), Combined modes, Elastosonography, 3D/4D and CnTI.

The ultrasound scanner is suitable for use in health institutions and is designed for ultrasound practitioners.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the 7600 Ultrasound System are the same as those of predicate device, cleared via K243253.

Technological Comparison

21 CFR 807.92(a)(6)

7600 Ultrasound System is substantially equivalent to the predicate device with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

• The systems are all intended for diagnostic ultrasound imaging.
• The proposed 7600 Ultrasound System and the predicate device have the same clinical use.
• The proposed 7600 Ultrasound System and the predicate device have the same intended use.
• The proposed 7600 Ultrasound System and the predicate device have the same imaging modes and modes of operation.
• The proposed 7600 Ultrasound System and the predicate device have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
• All the Esaote's ultrasound systems are equipped with the same software pack with specific configurations to control and set the system in accordance with user needs and hardware capabilities.
• The proposed 7600 Ultrasound System and the predicate device have been designed in compliance with approved electrical and physical safety standards.
• The proposed 7600 Ultrasound System is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
• The proposed 7600 Ultrasound System has acoustic power levels which are below the applicable FDA limits.
• The proposed 7600 Ultrasound System implement Microsoft Windows 10 operating system, exactly like the predicate device.
• The proposed 7600 Ultrasound System and the predicate devices manage the same probes.
• The proposed 7600 Ultrasound System is a new portable version of the cart-based 6600 Ultrasound System previously cleared under K243253. The modification involves a change in the physical design and shape to enable portability, while maintaining the same core components, technological characteristics and intended use.
• The proposed 7600 Ultrasound System includes a new software version that combines features FDA-cleared and already available in the predicate device 6600 Ultrasound Systems and on the reference device 6450 Ultrasound system. No new functionalities have been introduced in the current software release compared to the version previously cleared.

All necessary performance tests have been performed to ensure the safety of the subject device. Results of these tests show that the proposed subject device meets its intended use and does not raise new questions of safety or effectiveness.

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

Summary of Non-Clinical Tests:

7600 Ultrasound System has been tested according to the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.
- IEC 60601-1-2 Edition 4.1 2020-09, 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 Edition 3.2 2020-07, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 60601-2-37 Edition 2.1 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).
- IEC 62304 Edition 1.1 2015-06, Medical device software — Software life cycle processes

Verification and Validation testing results confirmed that all predefined acceptance criteria were successfully met.

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

Conclusion:

The 7600 Ultrasound System is substantially equivalent to its predicate device currently marketed and conform to applicable medical device safety and performance standards.