Esaote S.p.A.
% Alberto Carcagni
Regulatory Officer
Via Enrico Melen 77
Genoa, 16152
ITALY

September 16, 2021

Re: K212021
Trade/Device Name: 6430 MyLabX75, 6430 MyLab XPro75
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: June 15, 2021
Received: June 28, 2021

Dear Alberto Carcagni:

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Jessica Lamb

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212021

Device Name
6430 MyLabX75, 6430 MyLab XPro75

Indications for Use *(Describe)*
The multifunctional ultrasound scanner MyLabX75 Family is used to collect, display, and analyze ultrasound images during ultrasound imaging procedures in combination with supported echographic probes

-Cardiac [Adult and Pediatric]
-Vascular [Neonatal, Adult Cephalic, Vascular generic]
-General Imaging [Abdominal, Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organs (Testicles), Thyroid, Urological] with invasive access Intraoperative (Abdominal), Laparoscopic,Transrectal.
-Women Health [OB/Fetal, Gynecology with invasive access (Transrectal, Transvaginal)]

The equipment provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.
The ultrasonic medical diagnostic equipment is intended to be connected to mechanical and electronic ultrasound probes (convex array, linear array and phased array) and Doppler probes.

The Fiber Guidance option assists ultrasound guidance in the phases of insertion and positioning of the introducer needle and optical fiber and procedure monitoring.

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.

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K212021

Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

Submitter Information

Esaote S.p.A.
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Date: 15th Jun, 2021

807.92(a)(2)

Device

Common Name:	Ultrasound Imaging System	
Trade Name:	6430 MyLabX75, 6430 MyLab XPro75	
Classification Name(s):	Ultrasound Pulse Doppler Imaging System	892.1550
	Ultrasound Pulse Echo Imaging System	892.1560
	Transducer, Ultrasonic, Diagnostic	892.1570
Classification Number:	90IYN, 90IYO, 90ITX	

807.92(a)(3)

Predicate Device(s)

Predicate	510(k)	Device	Owner
Primary	K192157	6450 – MyLabX8	Esaote S.p.A.

This predicate has not been subject to a design-related recall

807.92(a)(4)

Device Description

Model 6430**,** commercial names MyLabX75 and MyLab XPro75, is a mainframe ultrasound system used to perform diagnostic general ultrasound studies. The primary modes of operation are: B-Mode, Tissue Enhancement Imaging (TEI), M-Mode, Multi View (MView), Doppler (both PW and CW), Color Flow Mapping (CFM), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM), 3D and 4D, Qualitative Elastosonography (ElaXto) and Quantitative Elastosonography (QElaXto).

Model 6430 has a software option integrated, called PLA, designed to support a radiological clinical ultrasound examination (first modality) and follow a percutaneous procedure providing additional image information from a second imaging modality (CT, MR, US and PET). The user is helped in assessing the patient anatomy by displaying the image generated by the 2nd modality.

Model 6430 is equipped with a LCD color display where acquired images and advanced image features are shown. Model 6430 control panel is equipped with a pull-out Qwerty alphanumeric keyboard that allows data entry. The touchscreen has an emulation of the Qwerty alphanumeric keyboard that allows data entry and has additional controls and mode-depending keys, integrated in the touchscreen.

Model 6430 can drive Phased Array (PA), Convex Array (CA), Linear Array (LA), Doppler and Volumetric probes.

Model 6430 is equipped with an internal Hard Disk Drive. Data can also be stored directly to external archiving media (Hard-Disk, PC, on server) via a LAN/USB port.

6430 project is mainly design change of 6450 devoted to reducing cost and to differentiate design and performances, 6430 will introduce in the Esaote's Mid-ultrasound tier functionalities that, at the moment are present only in our High -End Ultrasound tier, such as 2D Shear Wave Elastography (2D-SWE) and Virtual Navigator.

The marketing names for Model 6430 will be MyLabX75 and MyLab XPro75.

The difference between MyLabX75 and MyLab XPro75 is only in the licenses configuration: on MyLab XPro75 all the options are included while in the MyLabX75 some licenses can be ordered by customer.

807.92(a)(5)

Indications for Use/ Intended Use

The multifunctional ultrasound scanner MyLabX75 Family is used to collect, display, and analyze ultrasound images during ultrasound imaging procedures in combination with supported echographic probes

-Cardiac [Adult and Pediatric]
-Vascular [Neonatal, Adult Cephalic, Vascular generic]
-General Imaging [Abdominal, Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organs (Testicles), Thyroid, Urological] with invasive access Intraoperative (Abdominal), Laparoscopic,Transrectal.
-Women Health [OB/Fetal, Gynecology with invasive access (Transrectal, Transvaginal)]

The equipment provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.
The ultrasonic medical diagnostic equipment is intended to be connected to mechanical and electronic ultrasound probes (convex array, linear array and phased array) and Doppler probes.

The Fiber Guidance option assists ultrasound guidance in the phases of insertion and positioning of the introducer needle and optical fiber and procedure monitoring.

807.92(a)(6)

Technological Characteristics

Model 6430 employs the same fundamental technological characteristics as the predicate device.

Model 6430 is substantially equivalent to Esaote Model 6450 including the guide for fibre installation for Percutaneous Laser Ablation. The PLA option has been cleared with Virtual Navigator Option (echo-laser) via K192157.

The following Features, firstly cleared with Esaote 6440 high-end model, have been introduced on 6430 middle-end model:

- 2D Shear Wave Elastography (2D-SWE)
- PLA Echo guide for installation of fiber for laser ablation.
- Transducer element Check*

* The function Transducer Element Check, required by FDA (with Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, Guidance for Industry and Food and Drug Administration Staff, issued on June 27, 2019), is under development on 6430, with Esaote project PRJ000167, having Requirements defined in PRQ000229 and Software Requirements Specifications in SRS000160 documents.

The Transducer Element Check will be released on Esaote systems following the plan reported in Project Development Plan PDP000050.
All the mentioned documents are enclosed in section 1.7.5.7 of this submission.

The subject and predicate device are based on the following same technological elements:

- Clinical uses for which Esaote Model 6430 is designed are included in those of the Esaote Model 6450, already cleared via K192157.

- Models 6430 and 6450 ultrasound models provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

- Most part of the transducers for the use with the Esaote Model 6430 are also available with the Esaote Model 6450, already cleared via K192157.

- Models 6430 and 6450 ultrasound models provide similar measurements and analysis packages, with equal accuracy and precision.

- Models 6430 and 6450 ultrasound models have digital storage capabilities, including network connectivity.

- Model 6430 imaging modes are available on other FDA cleared ultrasound systems, for instance Esaote 6440 ultrasound model

- The Model 6430 QElaXto (Breast) and ElaXto (Thyroid) features are equivalent to the ones of Esaote's 6450, already cleared via K192157.

807.92(b)(1)

Summary of Non-Clinical Tests

The 6450 model 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 to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-2-37
- NEMA UD-2

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusions

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the Esaote Model 6430 ultrasound system should perform as intended in the specified use conditions.
MyLabX75 and MyLab XPro75 Models employ the same fundamental technological characteristics as the predicate devices.

All the features included in new 6430 MyLabX75 and MyLab XPro75 have been cleared in the predicated device 6450.
The 6430 project is mainly a design change of 6450 (previously cleared by FDA via K192157) devoted to reducing cost and to differentiate design and performances.
MyLabX75 will introduce in the Esaote's Mid-ultrasound tier functionalities that, at the moment are present only in our High -End Ultrasound tier, such as 2D Shear Wave Elastography (2D-SWE) and PLA fiber guide that helps in the insertion of the fiber guide but is not involved in the control of the laser ablation.
The detailed features comparison between MyLabX75 and MyLabX8 is reported in section 1.5 Predicate Device Comparison, of this submission.

We can conclude that the MyLabX75 and MyLab XPro75 Models are substantially equivalent to primary predicate device, Esaote MyLabX8, cleared via K192157.