Esaote, S.p.A.
% Piet de Jong
Regulatory Affairs Manager
via Enrico Melen 77
16152 Genoa
ITALY

November 22, 2019

Re: K192157
Trade/Device Name: 6450 Ultrasound system
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 1, 2019
Received: August 9, 2019

Dear Piet de Jong:

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); 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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192157

Device Name
6450 Ultrasound System

Indications for Use *(Describe)*
Esaote's Model 6450, commercial names MyLabX8 and MyLabX8 eXP, is intended to perform diagnostic general ultrasound studies including: Fetal, Abdominal, lntraoperative (Abdominal), Laparoscopic, Pediatric, Small organ, Neonatal, Neonatal Cephalic, Adult Cephalic, Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Urological, Cardiovascular Adult, Cardiovascular Pediatric, Transesophageal (cardiac), Peripheral Vessel.
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 Virtual Navigator software option for Esaote 6450 system is intended to support a radiological clinical ultrasound examination (first modality) and follow percutaneous procedures or surgical operations providing additional image information from a second imaging modality (CT, MR, US and PET). The second modality provides additional security in assessing the morphology of the ultrasound image.
Virtual Navigator can be used in the following application: Abdominal, Gynecological, Musculoskeletal, Obstetrics, Pediatric, Urologic, Small Organs, Peripheral Vascular and Transcranial for radiological examinations only.
The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.
The Virtual Navigator tracking system is contraindicated for patients, operators, personnel and other people who use an electronic life support device (such as a cardiac pacemaker or defibrillator).

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.**

K192157

# 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.
Via Enrico Melen 77
16152 Genova
Italy

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Date: August 1, 2019

807.92(a)(2)

## Device

| | | |
|---|---|---|
| Common Name: | Ultrasound Imaging System | |
| Trade Name: | 6450 Ultrasound System | |
| 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 | K173291 | 6440 – MyLab9 eXP | Esaote S.p.A. |

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

807.92(a)(4)

## Device Description

Model 6450**,** commercial names MyLabX8 and MyLabX8 eXP, 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 6450 has the Virtual Navigator software option integrated, 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 6450 is equipped with a LCD color display where acquired images and advanced image features are shown. Model 6450 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 6450 can drive Phased Array (PA), Convex Array (CA), Linear Array (LA), Doppler and Volumetric probes.

Model 6450 is equipped with an internal Hard Disk Drive. Data can also be stored directly to external archiving media (Hard-Disk, PC, server) via a LAN/USB port.

The marketing names for Model 6450 will be MyLabX8 and MyLabX8 eXP.

807.92(a)(5)

## Indications for Use/ Intended Use

Esaote's Model 6450, commercial names MyLabX8 and MyLabX8 eXP, are intended to perform diagnostic general ultrasound studies including: Fetal, Abdominal, Intraoperative (Abdominal), Laparoscopic, Pediatric, Small organ, Neonatal, Neonatal Cephalic, Adult Cephalic, Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Urological, Cardiovascular Adult, Cardiovascular Pediatric, Transoesophageal (cardiac), Peripheral Vessel.

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 Virtual Navigator software option for Esaote 6450 system is intended to support a radiological clinical ultrasound examination (first modality) and follow percutaneous procedures or surgical operations providing additional image information from a second imaging modality (CT, MR, US and PET). The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Gynecological, Musculoskeletal, Obstetrics, Pediatric, Urologic, Small Organs, Peripheral Vascular and Transcranial for radiological examinations only.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system is contraindicated for patients, operators, personnel and other people who use an electronic life support device (such as a cardiac pacemaker or defibrillator).

807.92(a)(6)

## Technological Characteristics

Model 6450 employs the same fundamental technological characteristics as the predicate device.

Model 6450 is substantially equivalent to Esaote Model 6440 including the Virtual Navigator software option cleared via K173291.

New common Features include:

- Virtual Biopsy
- QElaXto (Breast)
- ElaXto (Thyroid)
- Management of probes C2-9 and E3-12. (technically, clinically and biologically equivalent, respectively to C1-8 and SE3133, already cleared via K173291)

- Breast Nav

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

- Clinical uses for which Esaote Model 6450 is designed are equivalent to those of the Esaote Model 6440, already cleared via K173291.

- Models 6450 and 6440 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 6450 are also available with the Esaote Model 6440, already cleared via K173291.

- Models 6450 and 6440 ultrasound models provide similar measurements and analysis packages, with equal accuracy and precision.

- Models 6450 and 6440 ultrasound models have digital storage capabilities, including network connectivity.

- Model 6450 imaging modes are available on other FDA cleared ultrasound systems, for instance Esaote 6440 ultrasound model

- The Model 6450 Virtual Biopsy, QElaXto (Breast) and ElaXto (Thyroid) features are equivalent to the ones of Esaote's 6440, already cleared via K173291.

- 6450 Breast Nav feature is based on the Virtual Navigator also available on 6440, already cleared via K173291.

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 6450 ultrasound system should perform as intended in the specified use conditions.