November 29, 2023

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

Re: K230179
Trade/Device Name: 6440 MyLabX90
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: October 27, 2023
Received: October 27, 2023

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 (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.

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

Yanna Kang, Ph.D.
Assistant Director
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K230179

Device Name
6440 MyLabX90

Indications for Use *(Describe)*

The multifunctional ultrasound scanner MyLabX90 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, Musculo-skeletal, 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.

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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"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) Summary K230179

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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Italy

Contact Person: Alberto Carcagnì, Regulatory Affairs Specialist
alberto.carcagni@esaote.com

Date: Latest modification on 27 September 2023

807.92(a)(2)

Devices

Common Name:	Ultrasound Imaging System	
Trade Name:	6440 MyLabX90	
Classification Name(s):	Ultrasound Pulse Doppler Imaging System	892.1550
	Ultrasound Pulse Echo Imaging System	892.1560
	Transducer, Ultrasonic, Diagnostic	892.1570
	Automated Radiological Image Processing Software	892.2050
Classification Number:	892.1550, 892.1560, 892.1570 and 892.2050	
Product Codes:	IYN, IYO, ITX and QIH	

807.92(a)(3)

Predicate Device(s)

Predicate	510(k)	Device	Owner
Primary	K173291	6440 – MyLab9	Esaote S.p.A.
Reference	K192157	6450 – MyLabX8	Esaote S.p.A.
Reference	K212021	6430 – MyLabX75	Esaote S.p.A.

Additional substantial equivalence information is provided in the substantial equivalence comparison table.

807.92(a)(4)

Device Description

The upgraded 6440 systems, MyLabX90 is a mainframe systems equipped with wheels allowing to move the system.
MyLabX90 scanners are based on a mainframe easily movable platform.
MyLabX90 scanners have four swiveling wheels, they have a range of height adjustments for one-time installation, the main screen can be easily moved due to an optional articulated arm. Due to their small footprint they can fit in any real-world clinical environment.
The possibility to adjust both the main screen, control panel and touchscreen brightness enables the use of MyLab in any environment even with really different lighting conditions:
from the really bright scenario of the operative room, to the dark scenario of the examination room, passing through the medium-light environment of the bed-side examination setting.
The primary modes of operation are for both models: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM), 3D and 4D. Model 6440 manages Qualitative Elastosonography (ElaXto).

Model 6440 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.

Model 6440 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 2nd 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 6440 is equipped with wireless capability.

Model 6440 is already cleared via K173291.

The marketing name for new devices of Model 6440 will be:

- MyLabX90

MyLabX90, defined herein, combines the cleared features of 6440 system with new capabilities, listed below:

1. Cardio Package with new **AUTO E.F.** The AutoEF, based on Artificial Intelligence, detects and track, automatically, the LV endocardial border to calculate LV Volumes (Diastolic Volume - Systolic Volume) and EF (Ejection Fraction). The software module (powered with A.I.) is registered by Pie Medical Imaging B.V. as Caas Qardia (K212376)
2. **eDetect for Breast Lesions contouring** function supports the operator by detecting the lesion contour (with A.I. algorithm) in Breast measurements, after that the operator has identified the region, with suspicious lesions, and applied the ROI marker. At the end of the detection the operator can confirm/edit the proposed contour or redraw it completely. In addition, several morphologic parameters (following Bi-Rads : shape, orientation and circumscribed) are automatically proposed to the customer and upon validation is inserted in the final report. The tool is available in Breast application.

3. **XStrain** allows clinicians to quantify endocardial velocities of contraction and relaxation and local deformation of the heart (Strain/Strain rate). Based on 2D speckle tracking technology with Angle-independent technology. A.I. Powered for auto border detection of left ventricle (LV).
4. The **QAI (Quality Attenuation Imaging)** application allows to perform a Colored Quantitative Attenuation analysis of tissues in Real-time. Based on the attenuation analysis along the ROI. In QAI attenuation parameter values are converted and color coded and displayed inside the Region Of Interest (ROI). A different set of palettes is available, with dynamic control and transparency.
5. The **Prostate Biopsy Stepper** is enabling the compatibility with CIVCO Classic and GfM MST50 steppers displaying a Grid Template overlays for precise guided-biopsies. The Stepper help stabilizes and follows accurate needle path during transperineal procedure. Stepper functionality is available in Fusion imaging / UroFusion environment.
6. **HyperDoppler**, based on Color Doppler Flow Mapping (CDFM) technology, provides different map representation to highlight the intracardiac flow properties
7. **Transducer Element Check**
8. New transducers **2CWL, 5CWL, CX 1-8, LX 3-15, LMX 4-20, PX 1-5** and **TE 3-8**
9. New biopsy kits **JSM-198** and **JSM-113**.

New verification tests and all the mentioned documents are enclosed in section 1.7.5.7 of this submission.

807.92(a)(5)

Indication for Use/ Intended Use

The multifunctional ultrasound scanner MyLabX90 is used to collect, display, and analyze ultrasound images during ultrasound imaging procedures in combination with supported echographic probes.

Table: Intended Purpose

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

Virtual Navigator is a MyLab option to support 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.

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Technological Characteristics

MyLabX90 employs the same fundamental technological characteristics as his predicate device Esaote 6440 model cleared via K173291.
Implemented options on the existing device are identical to the one of Esaote 6440 and 6450 models cleared via K173291 and K192157.

- Clinical uses for which Esaote 6440 model have been cleared by FDA via K173291 are not changed by 6440 Upgrades, to be cleared via this submission.
- Auto NT option on the upgraded 6440 system is identical to the one of Esaote 6440 model cleared via K173291.
- QPack, 4D STIC/XSTIC and MicroV options on the upgraded 6440 system are identical to one of Esaote 6440 model, cleared via K173291.
- The following probes management is added on the upgraded 6440 system:

Probe	**Cleared via**
C 2-9	K192157
E 3-12	K192157
IL 4-13	K161359
IOT342	K161359
LP 4-13	K161359
P 2-9	K190989
P2 5-13	K190989
SB3123	K161359
SL3116	K161359
2CWL (Continous Wave Doppler)	The present submission
5CWL (Continous Wave Doppler)	The present submission
CX 1-8	The present submission
LX 3-15	The present submission
LMX 4-20	The present submission
PX 1-5	The present submission
TE 3-8	The present submission

CX 1-8 is equivalent to cleared C 1-8, TE 3-8 transoesophageal probe is equivalent to cleared TEE022 Probe, LX 3-15 (previously known as LX 4-15) is equivalent to cleared L 3-11 Probe.
LMX 4-20 is equivalent for different aspects (functional, biological, technological) to the cleared probes LA523, LA435 and L 8-24. The introduction tests for new probes are included in section 1.7.5.7.
The biocompatibility tests for the new probe materials are included in section 1.7.3 Patient Contacting Material.

- The upgraded 6440 system offer a new monitor 24’ with HDR technology and a new touchscreen, these new screens are an evolution of the ones already cleared on 6440.
- The upgraded 6440 system works with Windows 10 Enterprise, operative system, exactly like previous Esaote 6440 and 6450 models, cleared via K173291 and K192157.

AI Summary of Testing: eDetect for Breast Lesions contouring

The acceptance criteria is aimed to demonstrate the statistical equivalence between automated and manual assessment of the Breast Lesion contour and BIRADS parameters assessment. Criteria, to establish the final positive or negative outcome of the validation:

Breast Lesion – IOU Contour
Acceptance Threshold: 0.85
Average Error < 0.15

BIRADS Parameters

Shape	*Orientation:*	*Circumscribed:*
Success Rate > 80%	Success Rate > 90%	Success Rate > 75%

The test results are in line with the acceptance criteria.

Test example for Esaote linear probe L4-15:

L 4-15

	Target [mm²]	Measured [mm²]	Absolute Difference [mm²]	Percentage Error(%)
A1	3.14	3	0.14	4.5
A2	12.57	11	1.57	12.5
A3	28.27	25	3.27	11.6

	Target [mm]	Measured [mm]	Absolute Difference [mm]	Percentage Error(%)
P1	6.28	6.8	0.52	8.3
P2	12.57	14.3	1.73	13.8
P3	18.85	20.4	1.55	8.2

The complete test report, with data source description, is available in section 1.7.5.

Demographics
Both Training and Test Datasets are based on female patients and report US images of breast examinations.

Clinical subgroups and confounders present in the dataset
Disease distribution for training dataset is 80% Benign, 20% Malignant. Disease distribution for test dataset is 80% benign cases and 20% malignant. There is no need to include in the training or in the validation dataset normal cases for the target of edge detection.

Equipment
The acquisition equipment is the Ultrasound system Esaote MyLabX9 and MyLabX90 with the Esaote linear transducers L4-15, L8-24, LX3-15, LMX4-20 and L3-11.

Images have been saved during exam and lesions contoured using standard sw provided on Esaote Mylab X9 US equipment. Data Annotation includes information about lesion size, morphology, position, vascularization, and diagnosis given by physician.

"Truthing" process

For the dataset, two certified radiologists performed data evaluation for the border contouring. Their experience has therefore matured within different structures, where they have operated independently and at different times. Each contributed to the annotation then reviewed the annotations of the other. A consensus reading was done whereby the two radiologists discussed if they agreed on or not.

The delivered data were archived and delivered in 2 separated repository and confirmed no overlap between the 2 data sets.

The test dataset is composed 100 Images with Measure collected from 20 different patients. These 20 patients were not involved in the collection of the training dataset in order to keep training and test sets separated.

Ensuring independence of test data from training data

Medical Center selected 450 different patients to collect **training dataset**, and, on each case, operators employed all the linear probes suitable for breast exams in order to save 828 images totally.

Test dataset has been collected selecting 20 patients not involved during the training dataset acquisition. Even in this case, exams were executed employing all the available linear breast probes to save 100 images totally.

AI Summary of Testing: Endocardium border segmentation

The Algorithm has been verified by determining the Dice coefficient using the segmented LV endocardium blood pool and the ground truth provided by the annotators following the expert guidelines.
As mentioned in 3.2, the mean Dice coefficient of the test cases must be larger than 0.9 and have a standard deviation of at most 0.03 (Leclerc, et al., 2019).
For the A2C/A4C algorithm, the average Dice coefficient is 0.95 with a standard deviation of 0.02 for the 200 individually segmented frames.

	End diastolic	End Systolic	Combined
A2C	0.95±0.02	0.94±0.03	0.95±0.02
A4C	0.96±0.02	0.95±0.02	0.95±0.02
Combined	0.95±0.02	0.94±0.02	0.95±0.02

Dice coefficient and standard deviation

The complete test report, with data source description, is available in section 1.7.5.

Demographics

For the development of the present algorithm, the echocardiographic images of patients with varying age and gender were included.
The total of 2616 time sequences (A2C, A3C and A4C combined) is originated by 399 patients.

Clinical subgroups and confounders present in the dataset

The data sets are acquired from subjects with a large variety of LV functional states, e.g. normal myocardial performance, myocardial infarction, myocardial hypertrophy.

Equipment

We aimed to collect data from different institutions, with different echocardiographic systems (the images were acquired by Esaote Mylab Alpha system and also from another ultrasounds scanner, not Esaote)
Annotations on the received ultrasound images are performed, using a customized CAAS Qardia 1.0 application.

"Truthing" process

There are no official guidelines for annotation of the LV blood pool endocardium contour. Therefore, an internal guideline was developed by using information gathered from external experts. These external experts are three cardiologists with more than 20 years and 30 years of experience and one clinical researcher with more than 5 years of experience with the analysis of cardiac ultrasound.

Ensuring independence of test data from training data

Description of training set, tuning set (if applicable), testing set

The A2C/A4C algorithm was trained on 1527 image frames, of which 1221 were used for training (training dataset) and 306 for validation (validation dataset).
The A2C/A4C algorithm was tested on 200 image frames (test dataset).
There is no overlap between training dataset, validation dataset and testing dataset.

807.92(b)(1)

Summary of Non-Clinical Tests

The 6440 upgraded system, MyLabX90, 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 60601-1:2005, AMD1:2012
- IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020
- IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012
- IEC 60601-2-37 (ed.2), am1 for use in conjunction with IEC60601-1 (ed.3), am1 with Corr1 and Corr2
- NEMA UD-2: 2004 (R2009)
- NEMA UD-3: 2004 (R2009)
- ETSI EN 301 489-17 V3.1.1 (2017-02)
- EN 62479 (2010-09)

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The upgraded 6440 system, MyLabX90, is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.