



Esaote S.p.A.
% Allison Scott, RAC
Associate Director
Navigant Consulting, Inc.
9100 Keystone Crossing, Suite 500
INDIANAPOLIS IN 46240

January 12, 2018

Re: K173291
Trade/Device Name: 6440 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 13, 2017
Received: October 16, 2017

Dear Ms. Scott:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue "FDA" watermark. To the right of the signature, the word "For" is printed in black.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173291

Device Name

6440 Ultrasound System

Indications for Use (Describe)

Esaote's Model 6440 is intended to perform diagnostic general ultrasound studies including: Fetal, Abdominal, Intraoperative (Abdominal), Pediatric, Small organs, Neonatal, Neonatal Cephalic, Adult Cephalic, Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Urological, Cardiovascular Adult, Cardiovascular Pediatric, Transoesophageal (cardiac), Peripheral Vessel.

The 6440 system 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 Virtual Navigator software option for Esaote model 6440 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 real time ultrasound image. Virtual Navigator can be used in the following applications: Abdominal, Gynecological, Musculoskeletal, Obstetrics, Pediatric, Urologic, Small Organs, Intraoperative (Abdominal), Intraoperative (Neurological), 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 be 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.

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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."

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N	N	N	N	N		N	N: 5, 6, 7, 11
Abdominal	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 10, 11, 12
Intraoperative (Abdominal)	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 11
Intraoperative Neurological										
Pediatric	N	N	N	N	N	N	N		N	N: 5, 6, 7, 11
Small Organs [1]	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 11
Neonatal Cephalic	N	N	N	N	N	N	N		N	N: 5, 6, 7
Adult Cephalic	N	N	N	N	N	N	N		N	N: 5, 6, 7
Cardiac [2]	N	N	N	N	N	N	N	N	N (9)	N: 5, 6, 7
Transesophageal (Cardiac)	N	N	N	N	N	N	N	N	N	N: 5, 6, 7
Transesophageal (Non Cardiac)										
Transrectal	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 11
Transvaginal	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 11
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N	N	N	N	N		N	N: 5, 6, 7, 11
Laparoscopic										
Musculo-skeletal Conventional [3]	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 11
Musculo-skeletal Superficial [3]	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 11
Other (Urological)	N	N	N	N	N	N	N		N	N: 5, 6, 7, 8, 11

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D / 4D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

C 1-8

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 7, 11
Abdominal	P	P	P		P	P	P		P	P: 5, 7, 8, 10, 11, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 7, 11
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 7, 11
Laparoscopic										P: 5, 7, 11
Musculo-skeletal Conventional	P	P	P		P	P	P		P	P: 5, 7, 11
Musculo-skeletal Superficial										P: 5, 7, 11
Other (Urological, Gynecological)	P	P	P		P	P	P		P	P: 5, 7, 11

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal – Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K163082

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

EC123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 7, 11
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Urological, Gynecological)	P	P	P		P	P	P		P	P: 5, 7, 8, 11

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M +PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K163082

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

IH 6-18

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 7, 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 7
Laparoscopic										
Musculo-skeletal Conventional	P	P	P		P	P	P		P	P: 5, 7, 8
Musculo-skeletal Superficial										
Other										

N: New indication, P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K163082

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CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Esote 6440 Ultrasound System 510(k)

L 3-11

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E: 5, 7
Abdominal	E	E	E		E	E	E		E	E: 5, 7, 8, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E: 5, 7
Small Organs [1]	E	E	E		E	E	E		E	E: 5, 7, 8
Neonatal Cephalic	E	E	E		E	E	E		E	E: 5, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5, 7
Laparoscopic										
Musculo-skeletal Conventional	E	E	E		E	E	E		E	E: 5, 7, 8
Musculo-skeletal Superficial	E	E	E		E	E	E		E	E: 5, 7, 8
Other										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTi) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTi) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Added under Appendix E
and to be cleared via this submission

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

L 4-15

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5, 7, 10, 11
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 7, 11
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 7, 11
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 7, 11
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 7, 11
Laparoscopic										
Musculo-skeletal Conventional	P	P	P		P	P	P		P	P: 5, 7, 8, 11
Musculo-skeletal Superficial	P	P	P		P	P	P		P	P: 5, 7, 8, 11
Other										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTi) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTi) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K163082

L 8-24

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

		<u>Mode of Operations</u>									
<u>Clinical Application</u>		B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric		N	N	N		N	N	N		N	N: 5, 7, 11
Small Organs [1]		N	N	N		N	N	N		N	N: 5, 7, 8, 11
Neonatal Cephalic		N	N	N		N	N	N		N	N: 5, 7, 11
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N		N	N: 5, 7, 11
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N		N	N: 5, 7, 8, 11
Musculo-skeletal Superficial		N	N	N		N	N	N		N	N: 5, 7, 8, 11
Other											

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block
- [4] Combined modes are: B+M+PW+CFM+PD
- [5] Compound Imaging (Mview)
- [6] 3D
- [7] CMM
- [8] Elastosonography (ElaXto)
- [9] Includes contrast (CnTi) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border
- [10] Includes contrast (CnTi) in characterization of liver lesions
- [11] Virtual Navigator
- [12] Quantitative Elastosonography (QElaXto)

To be cleared via this submission

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

mC 3-11

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

		<u>Mode of Operations</u>									
<u>Clinical Application</u>		B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic											
Fetal											
Abdominal		N	N	N	N	N	N	N		N	N: 5, 7, 10, 11
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N	N		N	N: 5, 7, 11
Small Organs [1]		N	N	N		N	N	N		N	N: 5, 7, 8, 11
Neonatal Cephalic		N	N	N		N	N	N		N	N: 5, 7, 11
Adult Cephalic											
Cardiac [2]		N	N	N		N	N	N	N	N	N: 5, 7, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N		N	N: 5, 7, 11
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTi) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTi) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

To be cleared via this submission

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

P 1-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>		<u>Mode of Operations</u>									
		B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic											
Fetal											
Abdominal		N	N	N	N	N	N	N		N	N: 7, 10, 11
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organs [1]											
Neonatal Cephalic											
Adult Cephalic		N	N	N	N	N	N	N		N	N: 7, 11
Cardiac [2]		N	N	N	N	N	N	N	N	N	N: 7, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N	N	N	N	N		N	N: 7, 11
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block
- [4] Combined modes are: B+M+PW+CFM+PD
- [5] Compound Imaging (Mview)
- [6] 3D
- [7] CMM
- [8] Elastosonography (ElaXto)
- [9] Includes contrast (CnTi) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border
- [10] Includes contrast (CnTi) in characterization of liver lesions
- [11] Virtual Navigator
- [12] Quantitative Elastosonography (QElaXto)

To be cleared via this submission

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S2MCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block
- [4] Combined modes are: B+M+PW+CFM+PD
- [5] Compound Imaging (Mview)
- [6] 3D
- [7] CMM
- [8] Elastosonography (ElaXto)
- [9] Includes contrast (CnTl) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border
- [10] Includes contrast (CnTl) in characterization of liver lesions
- [11] Virtual Navigator
- [12] Quantitative Elastosonography (QElaXto)

Previously cleared via K162290

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

S5MCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block
- [4] Combined modes are: B+M+PW+CFM+PD
- [5] Compound Imaging (Mview)
- [6] 3D
- [7] CMM
- [8] Elastosonography (ElaXto)
- [9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border
- [10] Includes contrast (CnTI) in characterization of liver lesions
- [11] Virtual Navigator
- [12] Quantitative Elastosonography (QElaXto)

Previously cleared via K162290

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

SB2C41

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 7, 8, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 7
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional	P	P	P		P	P	P		P	P: 5, 7
Musculo-skeletal Superficial										
Other (Urological, Gynecological)	P	P	P		P	P	P		P	P: 5, 7

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K161359

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

SHFCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular			P							
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block
- [4] Combined modes are: B+M+PW+CFM+PD
- [5] Compound Imaging (Mview)
- [6] 3D
- [7] CMM
- [8] Elastosonography
- [9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border
- [10] CnTI
- [11] Virtual Navigator
- [12] Quantitative Elastosonography (QElaXto)

Previously cleared via K162290

SI2C41

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows

<u>Clinical Application</u>	<u>Mode of Operations</u>									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 7, 11
Abdominal	P	P	P		P	P	P		P	P: 5, 7, 8, 10, 11
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 7, 11
Small Organs [1]										P: 5, 7, 11
Neonatal Cephalic	P	P	P		P	P	P		P	
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 7, 11
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional	P	P	P		P	P	P		P	P: 5, 7, 11
Musculo-skeletal Superficial										
Other (Urological, Gynecological)	P	P	P		P	P	P		P	P: 5, 7, 11

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K163082

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TLC 3-13 Convex

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological, Gynecological)	P	P	P		P	P	P		P	P: 5, 7, 8, 11

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K162290

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
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TLC 3-13 Linear

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 7, 8, 11

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography (ElaXto)

[9] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and

[10] Includes contrast (CnTI) in characterization of liver lesions

[11] Virtual Navigator

[12] Quantitative Elastosonography (QElaXto)

Previously cleared via K162290

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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: October 13, 2017

807.92(a)(2)

Device

Common Name:	Ultrasound Imaging System	
Trade Name:	6440 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	K163082	6200 – MyLabEight eXP	Esaote S.p.A.
Primary	K163082	Virtual Navigator Software	Esaote S.p.A.
Reference	K161359	6400 - MyLabSeven	Esaote S.p.A.
Reference	K150122	TomTec-Arena AutoLV	Tomtec Imaging Systems GMBH
Reference	K163077	LOGIQ E9 with XDclear	GE Healthcare

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

807.92(a)(4)

Device Description

Model 6440 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 Elastasonography (ElaXto) and Quantitative Elastasonography (QElaXto).

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 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 6440 is equipped with a LCD color display where acquired images and advanced image features are shown. Model 6440 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 6440 can drive Phased Array (PA), Convex Array (CA), Linear Array (LA), Doppler and Volumetric probes.

Model 6440 is equipped with an internal Hard Disk Drive and with a DVD-RW disk drive that can be used for image storage. Data can also be stored directly to external archiving media (Hard-Disk, PC, server) via a LAN/USB port.

The marketing name for Model 6440 will be called MyLab9 eXP.

807.92(a)(5)

Intended Use

Esaote's Model 6440 is intended to perform diagnostic general ultrasound studies including: Fetal, Abdominal, Intraoperative (Abdominal), Pediatric, Small organs, Neonatal, Neonatal Cephalic, Adult Cephalic, Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Urological, Cardiovascular Adult, Cardiovascular Pediatric, Transoesophageal (cardiac), Peripheral Vessel.

The 6440 system 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 Virtual Navigator software option for Esaote model 6440 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 real time ultrasound image. Virtual Navigator can be used in the following applications: Abdominal, Gynecological, Musculoskeletal, Obstetrics, Pediatric, Urologic, Small Organs, Intraoperative (Abdominal), Intraoperative (Neurological), 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 be 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)

Comparison of Technological Characteristics

Model 6440 employs the same fundamental technological characteristics as the predicate devices.

Model 6440 is substantially equivalent to Esaote Model 6200 including the Virtual Navigator software option cleared via K163082, and Esaote Model 6400 cleared via K161359

New features for the 6440 include:

Auto Ejection Function (Auto EF) feature of Model 6440 is equivalent to TomTec-Arena already cleared by FDA with K150122

QPack Function feature of Model 6440 is equivalent to LOGIQ E9 with XDclear already cleared by K163077

At a high level, the subject and predicate devices are based on the following same technological elements:

- Clinical uses for which Esaote Model 6440 is designed are equivalent to those of the Esaote Model 6200, already cleared via K163082.
- Models 6440, 6400, and 6200 ultrasound models provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.
- Transducers for use with the Esaote Model 6440 include transducers that are also available with the Esaote Model 6200, already cleared via K163082.
- Models 6440, 6400, and 6200 ultrasound models provide similar measurements and analysis packages, with equal accuracy and precision.
- Models 6440, 6400, and 6200 ultrasound models have digital storage capabilities, including network connectivity.
- Model 6440 imaging modes are available on other FDA cleared ultrasound systems, for instance Esaote 6400 and 6200 ultrasound models
- The Model 6440 Auto EF (Auto Ejection Fraction) feature is equivalent to TomTec- Arena function AutoLV, already cleared via K150122.
- The Model 6440 QPack feature is equivalent to LOGIQ E9 with XDclear, already cleared via K163077.

The following technological differences exist between the subject and predicate devices:

- The Model 6400 and 6200 ultrasound systems do not have Auto EF or QPack features
- The Virtual Navigator feature is not available on the TomTec or LOGIQ E9 reference devices

807.92(b)(1)

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the transducers associated with the Model 6440 ultrasound system was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The ultrasound transducers are considered tissue contacting for a duration of less than 24 hours.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Model 6440 ultrasound system. The system complies with the IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Mechanical and Acoustic Testing

Acoustic output testing was conducted according to NEMA Standards Publication UD 2-2004 Revision 3 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA Standards Publication UD 3-2004 Revision 2 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

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 6440 ultrasound system should perform as intended in the specified use conditions.