



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

December 4, 2018

Re: K183191

Trade/Device Name: 6420 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: November 16, 2018
Received: November 19, 2018

Dear Allison 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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 in a cursive style. A large, faint "FDA" watermark is visible in the background behind the signature.

Robert A. 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)

K183191

Device Name

6420 Ultrasound System

Indications for Use (Describe)

Esaote's 6420 is intended to perform diagnostic general ultrasound studies including:

Fetal, Abdominal, Intraoperative (Abdominal), Laparoscopic, Pediatric, Small organs, 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 phase array) and Doppler probes.

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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6420

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P: 5, 7
Abdominal	P	P	P	P	P	P	P		P	P: 5, 7
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5
Adult Cephalic	P	P	P	P	P	P	P		P	P: 5
Cardiac [2]	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5 P: 7
Transvaginal	P	P	P		P	P	P		P	P: 5 P: 7
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5
Laparoscopic	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P		P	P	P		P	P: 5 P: 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+CW+CFM+PD

[5] Compound Imaging (Mview)

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

[7] 3D/4D

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

1	L 4-15
2	SI2C41
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4	SE3133
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6	IH 6-18
7	IL 4-13
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9	SB3123
10	SI3323
11	SI3235
12	SI2325
13	SI3332
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15	AC2541
16	SC3123
17	SE3123
18	AL2442
19	SI1543
20	SP2730
21	S2MCW
22	S5MCW
23	SB2C41
24	SHFCW
25	ST2612
26	IOT342

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,
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,
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,
Laparoscopic										
Musculo-skeletal Conventional	P	P	P		P	P	P		P	P: 5, 7,
Musculo-skeletal Superficial	P	P	P		P	P	P		P	P: 5, 7,
Other										

The L 4-15 probe is already cleared via K173291, to be added to 6420 via this submission

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

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

SI2C41

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P		P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
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
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P		P	P	P		P	P: 5

Previously cleared via K161168

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

[7] 3D / 4D

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

SL3116

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
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
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

Previously cleared via K161168

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

[7] 3D/4D

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

SE3133

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

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

Previously cleared via K161168

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

[7] 3D/4D

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

TLC 3-13

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

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

Previously cleared via K161168

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

[7] 3D/4D

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:

<u>Clinical Application</u>	<u>Mode of Operations</u>							Harmonic Imaging (TEI)	Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	
Ophthalmic									
Fetal	P	P	P		P	P	P	P	P: 5
Abdominal	P	P	P		P	P	P	P	P: 5
Intraoperative (Abdominal)	P	P	P		P	P	P	P	P: 5
Intraoperative Neurological									
Pediatric	P	P	P		P	P	P	P	P: 5
Small Organs [1]	P	P	P		P	P	P	P	P: 5
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
Laparoscopic									
Musculo-skeletal Conventional [3]	P	P	P		P	P	P	P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P	P	P: 5
Other (Urological)	P	P	P		P	P	P	P	P: 5

Previously cleared via K161168

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

[7] 3D/4D

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

IL 4-13

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

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P		P	P: 5	
Abdominal	P	P	P		P	P	P		P	P: 5	
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5	
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P	P: 5	
Small Organs [1]	P	P	P		P	P	P		P	P: 5	
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	
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5	
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5	
Other (Urological)											

Previously cleared via K161168

Previously cleared via K161168

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

[7] 3D/4D

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

LP 4-13

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal	P	P	P		P	P	P		P	P: 5	
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	P	P	P		P	P	P		P	P: 5	
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											
Previously cleared via K161168											

Previously cleared via K161168

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

[7] 3D/4D

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

SB3123

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 7
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 7
Transvaginal	P	P	P		P	P	P		P	P: 5, 7
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
Previously cleared via K161168										

Previously cleared via K161168

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

[7] 3D/4D

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

SL3323

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

Previously cleared via K161168

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

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

[5] Compound Imaging (Mview)

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

[7] 3D/4D

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

SL3235

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

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P	P: 5	
Small Organs [1]	P	P	P		P	P	P		P	P: 5	
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	
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5	
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5	
Other (Urological)											

Previously cleared via K161168

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

[7] 3D/4D

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

SL2325

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

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P	P: 5	
Small Organs [1]	P	P	P		P	P	P		P	P: 5	
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	
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5	
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5	
Other (Urological)											
Previously cleared via K161168											

Previously cleared via K161168

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

[7] 3D/4D

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

SL3332

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

Previously cleared via K161168

Previously cleared via K161168

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

[7] 3D/4D

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

SC3421

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
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
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P		P	P	P		P	P: 5

Previously cleared via K161168

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

[7] 3D/4D

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

AC2541

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P	P	P		P	P: 5
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	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P		P	P	P		P	P: 5

Previously cleared via K161168

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

[7] 3D/4D

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

SC3123

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										
Previously cleared via K161168										

Previously cleared via K161168

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

[7] 3D/4D

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

SE3123

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5
Transvaginal	P	P	P		P	P	P		P	P: 5
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5

Previously cleared via K161168

Previously cleared via K161168

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

[7] 3D/4D

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

AL2442

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

Previously cleared via K161168

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

[7] 3D/4D

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

SL1543

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

Previously cleared via K161168

Previously cleared via K161168

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

[7] 3D/4D

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

SP2730

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	
Abdominal	P	P	P	P	P	P	P		P	
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	
Small Organs [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	
Adult Cephalic	P	P	P	P	P	P	P		P	
Cardiac [2]	P	P	P	P	P	P	P	P	P	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

Previously cleared via K161168

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

[7] 3D / 4D

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

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 (AD)	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				P						
Laparoscopic										
Musculo-skeletal Conventional										
[3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

Previously cleared via K161168

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

[7] 3D/4D

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:

<u>Clinical Application</u>	<u>Mode of Operations</u>									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	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 [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

Previously cleared via K161168

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

[7] 3D/4D

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:

<u>Clinical Application</u>	<u>Mode of Operations</u>										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P		P		P: 5, 7
Abdominal	P	P	P		P	P	P		P		P: 5, 7
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)											

Previously cleared via K161168

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

[7] 3D/4D

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 (AD)	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 [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

Previously cleared via K161168

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

[7] 3D/4D

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

ST2612

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 (AD)	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)	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

Previously cleared via K161168

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

[7] 3D/4D

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IOT342

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 (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
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
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										
Previously cleared via K161168										

Previously cleared via K161168

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] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border.

[7] 3D/4D

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510(k) Submission
6420 Upgrade
Esaote S.p.A.

K183191

Special 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

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Date: November 16, 2018

807.92(a)(2)

Devices

Common Name: Ultrasound Imaging System

Trade Name: 6420 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	K161168	6420 – MyLabSix	Esaote Europe B.V.
Reference	K173291	6440 – MyLab 9 eXP	Esaote S.p.A.

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

807.92(a)(4)

Device Description

The upgraded 6420 system (MyLabX5) is compact mainframe system equipped with wheels allowing to move the system. The system sizes and weights allow them to be carried using the handle.

The primary modes of operation are: 2D, M-Mode, Continuous Wave Doppler (CW), Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler, Pulse Wave (PW) Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM), 3D and 4D.

6420 is equipped with a LCD color display where acquired images and advanced image features are shown. 6420 can drive Phased array, Convex array, Linear array, Doppler probes and Volumetric probes (Bi-Scan probes). Model 6420 control panel is equipped with a pull-out Qwerty alphanumeric keyboard that allows data entry.

6420 is equipped with wireless capability.

Model 6420 was previously cleared via K161168.

The upgraded 6420 system, defined herein, combines the cleared features of both the 6440 and 6420 systems with new capabilities, listed below:

1. Management of Strain 2D.
2. Addition of Auto NT option.
3. Addition Auto EF option
4. Management of probe L 4-15.
5. Addition of Full screen option.
6. Operative system Windows 10

The 6420 new version is manufactured under an ISO 9001 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use

Esaote's 6420 is intended to perform diagnostic general ultrasound studies including: Fetal, Abdominal, Intraoperative (Abdominal), Laparoscopic, Pediatric, Small organs, 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 phase array) and Doppler probes.

807.92(a)(6)

Technological Characteristics

The 6420 upgrade employs the same fundamental technological characteristics as their predicate devices.

The 6420 upgraded system is substantially equivalent to Esaote 6420 model cleared via K141486, and updated via K161168 clearance.

- Clinical uses for which Esaote 6420 and 6440 models have been respectively cleared by FDA via K161168 and K173291 are not changed by the new 6420 version, to be cleared via this submission.
- The management of Strain 2D on the upgraded 6420 system is identical to those of Esaote 6440 model, cleared via K173291.
- Auto NT option on the upgraded 6420 system is identical to the one of Esaote 6440 model, cleared via K173291.
- Auto EF (Ejection fraction) option on the upgraded 6420 system is identical to the one of Esaote 6440 model, cleared via K173291.
- The probe L 4-15 management, added on the upgraded 6420 system has already cleared via K173291.
- The upgraded 6420 system offer Full screen mode, identical to the one of Esaote 6440 model, cleared via K173291.
- The upgraded 6420 system works with Windows 10 Enterprise LTSB, operative system, exactly like Esaote 6440 model, cleared via K173291.

807.92(b)(1)

Summary of Non-Clinical Tests

The upgraded 6420 system 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 60601-2-37
- NEMA UD-3 - Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 - Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The upgraded 6420 system is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.