



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Esaote Europe B.V.
% Allison Scott, RAC
Managing Consultant
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

September 2, 2016

Re: K161168
Trade/Device Name: MyLabSix Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 1, 2016
Received: August 2, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the FDA logo.

For

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)

K161168

Device Name

MyLabSix Ultrasound System

Indications for Use (Describe)

Esaote's MyLabSix ultrasound system is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal, Laparoscopic and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

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:

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	P	P: 5, 7	
Abdominal	P	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	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 N: 7	
Transvaginal	P	P	P		P	P	P		P	P: 5 N: 7	
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5	
Laparoscopic	N	N	N		N	N	N		N	N: 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 N: 7	

6420 is already cleared via K141486 and to be cleared with 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) 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)

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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	E	E	E		E	E	E		E	E: 5
Abdominal	E	E	E		E	E	E		E	E: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E: 5
Small Organs [1]	E	E	E		E	E	E		E	E: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E: 5
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E: 5
Other (Urological)	E	E	E		E	E	E		E	E: 5

The SI2C41 probe is added under Appendix E and to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) 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	E: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	E: 5
Small Organs [1]	P	P	P		P	P	P		P	E: 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	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	E: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	E: 5
Other (Urological)										

The SL3116 probe is already cleared via K101605 and added under Appendix E

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 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:

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	E	E	E		E	E	E	E	E	E: 5	
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organs [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	E	E	E		E	E	E	E	E	E: 5	
Transvaginal	E	E	E		E	E	E	E	E	E: 5	
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	E	E	E		E	E	E	E	E	E: 5	

The SE3133 probe is added under Appendix E and to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) 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									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (HEI)	Other (specify)
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E; 5
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	E	E	E		E	E	E		E	E; 5
Transvaginal	E	E	E		E	E	E		E	E; 5
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	E	E	E		E	E	E		E	E; 5

The TLC 3-13 probe is added under Appendix E and to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) 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:

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	E	E	E		E	E	E		E	E:5
Abdominal	E	E	E		E	E	E		E	E:5
Intraoperative (Abdominal)	E	E	E		E	E	E		E	E:5
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E:5
Small Organs [1]	E	E	E		E	E	E		E	E:5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E:5
Laparoscopic										
Musculo-skeletal Conventional	E	E	E		E	E	E		E	E:5
[3]										
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:5
Other (Urological)	E	E	E		E	E	E		E	E:5

The IH 6-18 probe is added under Appendix E and to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

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

The IL 4-13 probe is added under Appendix E and to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) 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:

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	N	N	N		N	N	N	N	N	N: 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	N	N	N		N	N	N	N	N	N: 5	
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

The LP 4-13 probe is to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnT1) 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:

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	N	N	N		N	N	N		N	N: 5, 7	
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organs [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	N	N	N		N	N	N		N	N: 5, 7	
Transvaginal	N	N	N		N	N	N		N	N: 5, 7	
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	N	N	N		N	N	N		N	N: 5, 7	

The SB3123 probe is to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) 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:

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	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)										

The SL3323 probe is already cleared via K141486

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 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										
	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	P	P	P		P	P	P	P	P	P: 5	
Small Organs [1]	P	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	P: 5	
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P	P	P	P: 5	
Musculo-skeletal Superficial [3]	P	P	P		P	P	P	P	P	P: 5	
Other (Urological)											

The SL3235 probe is already cleared via K141486

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 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										
	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	E	E	E		E	E	E	E	E	E: 5	
Small Organs [1]	E	E	E		E	E	E	E	E	E: 5	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E	E	E	E: 5	
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E	E	E	E: 5	
Musculo-skeletal Superficial [3]	E	E	E		E	E	E	E	E	E: 5	
Other (Urological)											

The SL2325 probe is added under Appendix E and to be cleared 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+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) 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:

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	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)										

The SL3332 probe is already cleared via K141486

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 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:

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	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

The SC3421 probe is already cleared via K141486

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 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:

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	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	

The AC2541 probe is already cleared via K141486

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 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:

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	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)										

The SC3123 probe is already cleared via K141486

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 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:

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: 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	

The SE3123 probe is already cleared via K141486

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 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:

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	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)										

The AL2442 probe is already cleared via K141486

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 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:

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	P	P	P		P	P	P	P	P	P: 5	
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	P	P	P: 5	
Small Organs [1]	P	P	P		P	P	P	P	P	P: 5	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	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	P: 5	
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P	P	P	P: 5	
Musculo-skeletal Superficial [3]	P	P	P		P	P	P	P	P	P: 5	
Other (Urological)											

The SL1543 probe is already cleared via K141486

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 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:

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	
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)										

The SP2730 probe is already cleared via K141486

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 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)											

The S2MCW probe is already cleared via K141486

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

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

The S5MCW probe is already cleared via K141486

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 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:

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, 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)										

The SB2C41 probe is already cleared via K141486

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

The SHFCW probe is already cleared via K141486

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 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:

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]											
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)											

The ST2612 probe is already cleared via K141486

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 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)

IOT342

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	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)											

The IOT342 probe is already cleared via K141486

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 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)

510(k) Summary

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

807.92(a)(1)

Submitter Information

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807.92(a)(2)

Trade Name: MyLabSix Ultrasound System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse Doppler imaging system 892.1550
Ultrasonic pulsed echo imaging system 892.1560
Diagnostic ultrasonic transducer 892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

Predicate Device(s)

Predicate	510(k)	Device	Owner
Primary	K141486	6420 – MyLabSix	Esaote Europe B.V.
Reference	K142008	6400 – MyLabSeven	Esaote S.p.A.
Reference	K101605	8100 – MyLabOne	Esaote Europe B.V.
Reference	K113156	SonoSite Edge	Fujifilm SonoSite, Inc.

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

Device Description

The MyLabSix is a mainframe ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Amplitude Doppler (AD), Tissue Enhancement Imaging (TEI), Multi View (MView), Tissue Velocity Mapping (TVM), Color Flow Mapping (CFM), Pulse Wave Doppler, 3D and 4D.

The MyLabSix is equipped with a free orientable LCD Color Display where acquired images and advanced images are shown. The MyLabSix is also equipped with a height adjustable/rotating keyboard.

A second LCD Display for additional controls and mode-depending keys, includes touch screen technology and is integrated in the control panel.

The MyLabSix can drive phased (PA), convex (CA), linear array (LA) probes, Doppler probes and Volumetric probes.

The MyLabSix is equipped with an internal Hard Disk 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 MyLabSix is already cleared via K141486.

The MyLabSix Upgrade, defined herein, combine the cleared features of MyLabSix system with new software capabilities, listed below:

1. Management of motorized probes (Bi-Scan probes) that allow volumetric acquisition in 3D/4D mode for Transrectal/Urologic and Transvaginal applications
2. Management of Laparoscopic application
3. Implementation of the Needle Visibility feature
4. Implementation of the on-board tutorial MyLibrary feature

The MyLabSix Upgrade is manufactured under an ISO 9001 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's **MyLabSix** ultrasound system is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal, Laparoscopic and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

Esaote Europe's MyLabSix Upgrade employs the same fundamental technological characteristics as its predicate devices. The MyLabSix Upgrade is substantially equivalent to Esaote Europe's MyLabSix already cleared via K141486, Esaote's MyLabSeven already cleared via K111302, K132231, K132466 and K142008, Esaote Europe's MyLabOne already cleared via K101605 and to SonoSite Edge already cleared via K113156.

- Clinical uses for which the MyLabSix, cleared via K141486, is designed are not changed by the MyLabSix Upgrade, to be cleared via this submission.
- Clinical uses for which the MyLabSix Upgrade is designed are equivalent to those of MyLabSeven, already cleared via K142008.
- The MyLabSix Upgrade for managing Laparoscopic application is equivalent to those of MyLabSeven already cleared via K142008.
- The MyLabSix Upgrade for managing of motorized probes (Bi-Scan probes) that allow volumetric acquisition in 3D/4D mode for Transrectal/Urology and Transvaginal applications is equivalent to those of MyLabSeven, already cleared via K142008.
- The MyLabSix Upgrade including the Needle Visibility feature is equivalent to those of SonoSite Edge, already cleared via K113156.

- The MyLabSix Upgrade including the on-board tutorial MyLibrary feature, that provide application aid and tips in the use of the system during procedures is equivalent to those of MyLabOne, already cleared via K101605.
- The MyLabSix Upgrade, MyLabSix, MyLabSeven, MyLabOne and SonoSite Edge are designed to meet the IEC60601-1 and the IEC60601-2-37 safety requirements.
- The MyLabSix Upgrade, MyLabSix, MyLabSeven, MyLabOne and SonoSite Edge provides an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.
- The MyLabSix Upgrade, MyLabSix, MyLabSeven, MyLabOne and SonoSite Edge provide a similar measurements and analysis package, with equal accuracy and precision.
- The MyLabSix Upgrade, MyLabSix, MyLabSeven and MyLabOne have digital storage capabilities, including Network connectivity.
- The MyLabSix Upgrade image modes are available on other FDA cleared ultrasound systems, for instance MyLabSeven.

807.92(b)(1)

Summary of Non-Clinical Tests

The MyLabSix Upgrade 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 Ed. 3.0 (2005-12) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Corrigendum 1:2006 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Corrigendum 2:2007 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Ed. 3.0 (2007-03) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and Tests.
- IEC 60601-2-37 Ed. 2.0 (2007-08) Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

- NEMA Standards Publication UD 2-2004 Revision 3 (R2009)
Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- 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)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The MyLabSix Upgrade is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.