



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

Esaote S.p.A  
% Allison Scott, RAC  
Managing Consultant  
Navigant Consulting, Inc.  
9001 Wesleyan Road, Suite 200  
INDIANAPOLIS IN 46268

July 19, 2016

Re: K161359  
Trade/Device Name: 6400 Ultrasound System, 7400 Ultrasound System, 7410 Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: May 12, 2016  
Received: May 16, 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)

Device Name

6400 Ultrasound System, 7400 Ultrasound System, 7410 Ultrasound System

Indications for Use (Describe)

Esaote's Model 6400 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. Model 6400 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.

Esaote's Model 7400 is a compact 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. Model 7400 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.

Esaote's Model 7410 is a compact 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. Model 7410 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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**6400**

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 (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)						
Ophthalmic															
Fetal	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5, 6
Abdominal	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5, 6
Intraoperative (Abdominal)	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Intraoperative Neurological															
Pediatric	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Small Organs [1]	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Cardiac [2]	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Cardiac) [2]	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Non Cardiac)															
Transrectal	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5, 6
Transvaginal	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5, 6
Transurethral															
Intravascular															
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Laparoscopic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
[3]															
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5
Other (Urological)	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P: 5 N: 6

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008 and to be cleared with this submission

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

# 7400

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008 and to be cleared with this submission

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

# 7410

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 (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal	P	P	P	P	P	P	P	P	P	P	P	P: 5, 6
Abdominal	P	P	P	P	P	P	P	P	P	P	P	P: 5, 6
Intraoperative (Abdominal)	N	N	N	N	N	N	N	N	N	N	N	N: 5
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P	P	P	P: 5
Small Organs [1]	P	P	P	P	P	P	P	P	P	P	P	P: 5
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	P	P: 5
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	P	P: 5
Cardiac [2]	P	P	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Cardiac) [2]	P	P	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Non Cardiac)												
Transrectal	P	P	P	P	P	P	P	P	P	P	P	P: 5 N: 6
Transvaginal	P	P	P	P	P	P	P	P	P	P	P	P: 5 N: 6
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	P	P: 5
Laparoscopic	N	N	N	N	N	N	N	N	N	N	N	N: 5
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P	P	P	P	P	P: 5
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P	P	P	P	P	P: 5
Other (Urological)	P	P	P	P	P	P	P	P	P	P	P	P: 5 N: 6

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077 and to be cleared with this submission

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

	Model			New	
	6400 (96ch) MyLabSeven K142008	7400 (96ch) MyLabAlpha K142008	7410 (64 ch) MyLabGamma K142077		
1	SP2430	1	1		
2	SP2442	1	1		
3	SP2730		1		
4	AL2442	1	1		
5	AL2443	1	1		
6	SL1543	1	1		
7	SL2325	1	1		
8	SL3116	1	1		
9	SL3235		1		
10	SL3323		1		
11	SL3332		1		
12	AC2541	1	1		
13	SC3123	1	1		
14	SC3421		1		
15	SI2C41	1	1	1	
16	SE3123	1	1		
17	SE3133	1	1	1	
18	IOT342	1	1		
19	IH 6-18	1	1	1	
20	IL 4-13	1	1	1	
21	LP 4-13	1	1	1	
22	TLC 3-13	1	1	1	
23	S2MCW	1	1		
24	S5MCW	1	1		
25	SHFCW	1	1		
26	S2MPW	1	1		
27	ST2613	1	1		
28	ST2612	1	1		
29	SB2C41	1	1		
30	SB3123	1	1		
31	LA435	1			
32	LA523	1			
33	CA430	1			
34	EC1123	1	1		
35	LP323	1			
36	TRT33	1			
37	IOT332	1			
38	IOE323	1			
39	BC431	1			
40	BC441	1			
41	BE1123	1			
		<b>36</b>	<b>26</b>	<b>24</b>	<b>6</b>



## SP2430 (6400 and 7400 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal	P	P	P	P	P	P	P		P	P: 5	
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]											
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 (7)	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]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008

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

## SP2442 (6400 and 7400 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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	P: 5	
Small Organs [1]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P: 5	
Adult Cephalic											
Cardiac [2]	P	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	P: 5	
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008

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

# SP2730 (7410 system)

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

## AL2442 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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)											

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/4D

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

Previously cleared via K142077

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

## AL2443 (6400 and 7400 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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	E	E	E		E	E	E		E	E: 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)											

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/4D

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

Previously cleared via K142008

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

## SL1543 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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)											

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/4D

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

Previously cleared via K142077

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

## SL2325 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P	P: 5	
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)											

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/4D

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

Previously cleared via K142077

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

# SL3116 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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	E	E	E		E	E	E	E	E	E: 5
[3]										
Musculo-skeletal Superficial [3]	E	E	E		E	E	E	E	E	E: 5
Other (Urological)										

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K133905

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



# SL3235 (7410 system)

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

# SL3323 (7410 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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	P	P	P		P	P	P	P	P	P: 5	
[3]											
Musculo-skeletal Superficial [3]	P	P	P		P	P	P	P	P	P: 5	
Other (Urological)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

# SL3332 (7410 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal	P	P	P		P	P	P		P	P: 5	
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	P	P	P		P	P	P		P	P: 5	
[3]											
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5	
Other (Urological)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

## AC2541 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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

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/4D

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

Previously cleared via K142077

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

## SC3123 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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]	E	E	E		E	E	E		E	E: 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]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

# SC3421 (7410 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal	P	P	P		P	P	P		P	P: 5	
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	P	P	P		P	P	P		P	P: 5	
[3]											
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: 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/4D

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

Previously cleared via K142077

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

## SI2C41 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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	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	

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/4D

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

To be cleared with this submission

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

## SE3123 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P		P	P	P		P	P: 5	

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/4D

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

Previously cleared via K142077

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



## SE3133 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	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

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/4D

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

To be cleared with this submission

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

# IOT342 (6400 and 7400 systems)

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

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	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)										

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/4D

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

Previously cleared via K142008

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

## IH 6-18 (6400 and 7400 systems)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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)	E	E	E		E	E	E		E	E: 5

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/4D

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

To be cleared with this submission

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

# IH 6-18 (7410 system)

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 (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal	E	E	E		E	E	E		E		E: 5	
Abdominal	E	E	E		E	E	E		E		E: 5	
Intraoperative (Abdominal)	N	N	N		N	N	N		N		N: 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	

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/4D

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

To be cleared with this submission

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

## IL 4-13 (6400 and 7400 systems)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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)										

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/4D

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

To be cleared with this submission

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

## IL 4-13 (7410 system)

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 (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal	E	E	E		E	E	E		E		E: 5	
Abdominal	E	E	E		E	E	E		E		E: 5	
Intraoperative (Abdominal)	N	N	N		N	N	N		N		N: 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)												

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/4D

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

To be cleared with this submission

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

## LP 4-13 (7400 and 7410 systems)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	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: 5
Musculo-skeletal Conventional										
[3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

To be cleared with this submission

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

## LP 4-13 (6400 system)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	E	E	E		E	E	E	E	E	E: 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	E	E	E		E	E	E	E	E	E: 5
Musculo-skeletal Conventional										
[3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

To be cleared with this submission

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



### TLC 3-13 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	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

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/4D

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

To be cleared with this submission

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

## S2MCW (6400, 7400 and 7410 systems)

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

## S5MCW (6400, 7400 and 7410 systems)

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

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

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/4D

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

Previously cleared via K142077

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

## SHFCW (6400, 7400 and 7410 systems)

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

## S2MPW (6400 and 7400 system)

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008

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

# ST2613 (6400 and 7400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organs [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	P	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)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008

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

# ST2612 (6400, 7400 and 7410 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organs [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	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)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142077

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

## SB2C41 (6400, 7400 and 7410 systems)

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

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6
Abdominal	P	P	P		P	P	P		P	P: 5, 6
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)										

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/4D

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

Previously cleared via K142077

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



# SB3123 (6400 and 7400 system)

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

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6
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, 6
Transvaginal	P	P	P		P	P	P		P	P: 5, 6
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5 N: 6

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/4D

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

Previously cleared via K142008 and via this submission

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

# SB3123 (7410 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal	E	E	E		E	E	E		E	E: 5, 6	
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 N: 6	

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/4D
- [7] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via K142008 and via this submission

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

# LA435 (6400 system)

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

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	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)										

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/4D

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

Previously cleared via K142008

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

## LA523 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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)											

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/4D

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

Previously cleared via K142008

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

## CA430 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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											
Small Organs [1]											
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	

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/4D

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

Previously cleared via K142008

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

## EC1123 (6400 and 7400 systems)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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	

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/4D

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

Previously cleared via K142008

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

## LP323 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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											
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	P: 5	
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008

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

# TRT33 (6400 system)

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

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

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/4D

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

Previously cleared via K142008

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



# IOT332 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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)											

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/4D

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

Previously cleared via K142008

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

## IOE323 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue 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)											

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/4D

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

Previously cleared via K142008

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

# BC431 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal	P	P	P		P	P	P		P	P: 5, 6	
Abdominal	P	P	P		P	P	P		P	P: 5, 6	
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)											

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/4D

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

Previously cleared via K142008

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

## BC441 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal	P	P	P		P	P	P		P	P: 5, 6	
Abdominal	P	P	P		P	P	P		P	P: 5, 6	
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)											

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/4D

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

Previously cleared via K142008

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

## BE1123 (6400 system)

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

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)	
Ophthalmic											
Fetal	P	P	P		P	P	P		P	P: 5, 6	
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, 6	
Transvaginal	P	P	P		P	P	P		P	P: 5, 6	
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

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

Previously cleared via K142008

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

## Traditional 510(k) Summary

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

807.92(a)(1)

### Submitter Information

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Date: April 19, 2016

807.92(a)(2)

### Devices

Common Name: Ultrasound Imaging System

Trade Name: 6400 Ultrasound System  
7400 Ultrasound System  
7410 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	K142008	6400 – MyLabSeven 7400 – MyLabAlpha	Esaote S.p.A.
Primary	K142077	7410 – MyLabGamma	Esaote S.p.A.
Reference	K110688	7340 – MyLab30 Gold	Esaote S.p.A.
Reference	K061961	ART.LAB	Esaote Europe B.V.
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.

807.92(a)(4)

### Device Description

Model 6400 is a mainframe system equipped with wheels allowing to move the system. Models 7400 and 7410 are portable systems equipped with a handle. The system sizes and weights allow them to be carried using its handle. The primary modes of operation are for both models: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM), 3D and 4D. Models 6400 and 7400 manages Qualitative Elastasonography (ElaXto).

All models 6400, 7400 and 7410 are equipped with a LCD color display where acquired images and advanced image features are shown. All models 6400, 7400 and 7410 can drive Phased array, Convex array, Linear array, Doppler probes and Volumetric probes (Bi-Scan probes). Model 6400 control panel is equipped with a pull-out Qwerty alphanumeric keyboard that allows data entry.

Models 7400 and 7410 the touchscreen has an emulation of the Qwerty alphanumeric keyboard that allows data entry. All models 6400, 7400 and 7410 are equipped with wireless capability. Models 7400 and 7410 have been designed to be powered by battery.

Both models 6400 and 7400 are already cleared via K142008.  
Model 7410 is already cleared via K142077.

Models 6400, 7400 and 7410 Upgrades, defined herein, combine the cleared features of both 6400, 7400 and 7410 systems with new capabilities, listed below:

1. Management of Intraoperative (Abdominal) application on 7410 Upgrade.
2. Management of Laparoscopic application on both 7400 and 7410 Upgrades.
3. Addition of Transrectal/Urology and Transvaginal applications in 3D/4D on 7410 Upgrade.
4. Addition of Urology application in 3D/4D on both 6400 and 7400 Upgrades.
5. Implementation of the QAS feature on 6400 and 7400 Upgrades.
6. Implementation of the Needle Visibility feature on all 6400, 7400 and 7410 Upgrades.
7. Implementation of the on-board tutorial MyLibrary feature on all 6400, 7400 and 7410 Upgrades.

The 6400, 7400 and 7410 Upgrades are manufactured under an ISO 9001 and ISO 13485 certified quality system.

807.92(a)(5)

## **Intended Use**

Esaote's Model 6400 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. Model 6400 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.

Esaote's Model 7400 is a compact 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. Model 7400 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.

Esaote's Model 7410 is a compact 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. Model 7410 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

The 6400, 7400 and 7410 Upgrades employ the same fundamental technological characteristics as their predicate devices.

The 6400 Upgrade model is substantially equivalent to Esaote 7340 model cleared via K110688, Esaote Europe's 8100 already cleared via K101605, Esaote Europe's ART.LAB already cleared via K061961, SonoSite Edge already cleared via K113156 and to Esaote 6400 model cleared by FDA via K142008.

The 7400 Upgrade model is substantially equivalent to Esaote 7340 model cleared via K110688, Esaote Europe's 8100 already cleared via K101605, Esaote Europe's ART.LAB already cleared via K061961, SonoSite Edge already cleared via K113156 and to Esaote 7400 model cleared by FDA via K142008.

The 7410 Upgrade model is substantially equivalent to Esaote 7340 model cleared via K110688, Esaote Europe's 8100 already cleared via K101605, SonoSite Edge already cleared via K113156, 7400 model cleared by FDA via K142008 and to Esaote 7410 model cleared by FDA via 142077.

- Clinical uses for which Esaote 6400, 7400 and 7410 models have been respectively cleared by FDA via K142008 and K142077 are not changed by 6400, 7400 and 7410 Upgrades, to be cleared via this submission.
- Clinical uses for which Esaote 6400 and 7400 Upgrades are designed are equivalent to those of 7340 model, cleared via K110688.
- Clinical uses for which Esaote 7410 Upgrade is designed are equivalent to those of Esaote 7340 model, cleared via K110688 and those of Esaote 7400 models, cleared by FDA via K142008.
- 7410 Upgrade for Intraoperative (Abdominal) application is equivalent to those of Esaote 7400 model, cleared via K142008.
- 7400 and 7410 Upgrades for managing Laparoscopic application are equivalent to those of Esaote 6400 model, cleared via K142008.
- 7410 Upgrade for managing Transrectal/Urology and Transvaginal applications in 3D/4D is equivalent to those of Esaote 7340 model, cleared via K110688.
- 6400 and 7400 Upgrade for managing Urology application in 3D/4D is equivalent to those of Esaote 7340 model, cleared via K110688.
- 6400, 7400 and 7410 Upgrades including the Needle Visibility feature is equivalent to those of SonoSite Edge, already cleared via K113156.
- 6400, 7400 and 7410 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 model 8100, already cleared via K101605.
- 6400 and 7400 Upgrades including the QAS feature is equivalent to those of ART.LAB software, already cleared via K061961.
- Esaote's 6400 Upgrade, 7400 Upgrade, 7410 Upgrade, 6400, 7400, 7410, 7340, 8100 and SonoSite Edge are designed to meet the IEC 60601-1 and IEC 60601-2-37 safety requirements.
- Esaote 6400 Upgrade, 7400 Upgrade, 7410 Upgrade, 6400, 7400, 7340, 8100 and SonoSite Edge ultrasound models provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

807.92(b)(1)

### **Summary of Non-Clinical Tests**

The 6400, 7400 and 7410 Upgrades have 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 6400, 7400 and 7410 Upgrades are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.