DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 4, 2016

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

Re: K153277
Trade/Device Name: 6200 Ultrasound System and 6250 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 13, 2016
Received: April 18, 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153277

Device Name
6200 Ultrasound System and 6250 Ultrasound System

Indications for Use *(Describe)*
Esaote's Model 6200 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), Intraoperative (Neurological), Laparoscopic and Other: Urologic. The 6200 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.

Esaote's Model 6250 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), Intraoperative (Neurological), Laparoscopic and Other: Urologic. The 6250 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.

The Virtual Navigator software option for Esaote models 6200 and 6250 is intended to support a radiological clinical ultrasound examination (first modality) and follow percutaneous procedures or surgical operations providing additional image information from a second imaging modality (CT, MR, US and PET). The second modality provides additional security in assessing the morphology of the ultrasound image.
Virtual Navigator can be used in the following application: Abdominal, Gynecological, Musculo-skeletal, Obstetrics, Pediatric, Urologic, Small Organs, Peripheral Vascular and Transcranial for radiological examinations only.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6200

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

[7] CMM

[8] Elastosonography

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

Previously cleared via k100931,
k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

6250

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

[7] CMM

[8] Elastosonography

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

Previously cleared via k103152, k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

CA123 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P		P	P: 5, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

CA421 (6250 system only)

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
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, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

CA430 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

CA431 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

C5-2 R13 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

CA541

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

CA621 (6250 systems only)

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
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, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

CA631 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

SC3123 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological	N	N	N		N	N	N		N	N: 5, 6, 7
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

SI2C41 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E: 5, 6, 7
Abdominal	E	E	E		E	E	E		E	E: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E: 5, 6, 7
Small Organs [1]	E	E	E		E	E	E		E	E: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	E	E	E		E	E	E		E	E: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E: 5, 6, 7
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E: 5, 6, 7
Other (Urological)	E	E	E		E	E	E		E	E: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

SC3121 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E: 5, 6, 7
Abdominal	E	E	E		E	E	E		E	E: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E: 5, 6, 7
Small Organs [1]	E	E	E		E	E	E		E	E: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	E	E	E		E	E	E		E	E: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E: 5, 6, 7
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E: 5, 6, 7
Other (Urological)	E	E	E		E	E	E		E	E: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LA332 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7; N: 8
Intraoperative (Abdominal)										
Intraoperative Neurological	N	N	N		N	N	N		N	N: 5, 6, 7
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LA435 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LA522 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LA523 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LA532 (6250 systems only)

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

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

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LA533 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LA923 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

SL3116 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological	N	N	N		N	N	N		N	N: 5, 6, 7
Pediatric										
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)										

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

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

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

PA023 (6200 and 6250 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]	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, 6, 7
Small Organs [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

PA122 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P: 5, 6, 7
Small Organs [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

PA230 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P	P	P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P	P	P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	P: 5, 6, 7
Cardiac [2]	P	P	P	P	P	P	P	P	P (9)	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

PA240 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P	P	P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological	N	N	N	N	N	N	N		N	N: 5, 6, 7
Pediatric	P	P	P	P	P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P	P	P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	P: 5, 6, 7
Cardiac [2]	P	P	P	P	P	P	P	P	P (9)	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

BC431 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P	P	P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

BC441 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5, 6, 7
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

BL433 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D/4D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

BE1123 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6, 7
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 7
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D
[7] CMM
[8] Elastosonography

[9] 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 (OIVD)

EC123 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	E	E	E		E	E	E		E	E: 5, 6, 7
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, 7; E: 8
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 7
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7; N:8

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

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM
[8] Elastosonography

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

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

EC1123 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
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, 7, 8
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 7; N: 8
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7; N:8

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

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

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

TEE022 (6200 and 6250 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]	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, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

TEE132 (6200 and 6250 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]	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, 6, 7
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
[7] CMM
[8] Elastosonography

[9] 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 (OIVD)

IOE323 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

IOT332 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5, 6, 7; N: 8
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Neonatal Cephalic	E	E	E		E	E	E		E	E: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7; E: 8
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM
[8] Elastosonography

[9] 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 (OIVD)

IOT342 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 7
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5, 6, 7
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

LP323 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 7
Small Organs [1]	P	P	P		P	P	P		P	P: 5, 6, 7
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7
Laparoscopic	P	P	P		P	P	P		P	P: 5, 6, 7
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

[7] CMM

[8] Elastosonography

[9] 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 (OIVD)

TRT33 (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6, 7, 8
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 7
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7

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

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM
[8] Elastosonography

[9] 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 (OIVD)

2CW (6200 and 6250 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]	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)										

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

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

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

5CW (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

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

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

HFCW (6200 and 6250 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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

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

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

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

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

S2MPW (6200 and 6250 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]	Color 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+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Elastosonography

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

Previously cleared via k132466

Prescription Use Only Per 21 CFR 801 Part D Concurrence of
CDRH, Office of In Vitro Diagnostics (OIVD)

Traditional 510(k) Summary

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

807.92(a)(1)

Submitter Information

Esaote S.p.A.
Via Siffredi 17
Genova, Italy 16153

Contact Person: Allison Scott
317.228.8719
allison.scott@navigant.com

Date: November 10, 2015

807.92(a)(2)

Devices

Common Name: Ultrasound Imaging System

Trade Name: 6200 Ultrasound System
6250 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	Device	Owner	510(k)
Primary	6200/6250	Esaote	K133905
Reference	6400	Esaote	K142008
Reference	Arietta 70	Hitachi Aloka	K134016
Reference	ART.LAB	Esaote Europe	K061961
Reference	Preirus	Hitachi Aloka	K093466

807.92(a)(4)

Device Description

Both 6200 and 6250 models are mainframe ultrasound systems used to perform diagnostic general ultrasound studies. The primary modes of operation are for both systems: B-Mode, Tissue Enhancement Imaging (TEI), M-Mode, Multi View (MView), Doppler (both PW and CW), Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM), 3D and 4D, Elastosonography. Both 6200 and 6250 are equipped with an LCD color display where acquired images and advanced image features are shown.

The Virtual Navigator is a software option designed to support a radiological clinical ultrasound examination (first modality) and follow a percutaneous procedure providing additional image information from a 2nd imaging modality (CT, MR, US and PET). The user is helped in assessing the patient anatomy by displaying the image generated by the 2nd modality.

6200 and 6250 Upgrades, defined herein, combine the cleared features of both 6200 and 6250 systems with new capabilities, listed below:

1. Management of Pulsed Wave (PW) Doppler probe on both 6200 and 6250 Upgrades.
2. Management of Quality Arterial Stiffness (QAS) on both 6200 and 6250 Upgrades.
3. Addition of Abdominal, Intraoperative abdominal, Transvaginal, Urology applications in Elastosonography analysis on both 6200 and 6250 Upgrades.
4. Management of Elastosonography measures on both 6200 and 6250 Upgrades.
5. Management of STIC (Spatio-Temporal Imaging Correlation) with volumetric Probes on both 6200 and 6250 Upgrades.
6. Management of Intraoperative (Neuro) application on both 6200 and 6250 Upgrades.

The 6200 and 6250 Upgrades are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use

Esaote's Model 6200 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), Intraoperative (Neurological), Laparoscopic and Other: Urologic. The 6200 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.

Esaote's Model 6250 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),), Intraoperative (Neurological), Laparoscopic and Other: Urologic. The 6250 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.

The Virtual Navigator software option for Esaote models 6200 and 6250 is intended to support a radiological clinical ultrasound examination (first modality) and follow percutaneous procedures or surgical operations providing additional image information from a second imaging modality (CT, MR, US and PET). The second modality provides additional security in assessing the morphology of the ultrasound image.
Virtual Navigator can be used in the following application: Abdominal, Gynecological, Musculo-skeletal, Obstetrics, Pediatric, Urologic, Small Organs, Peripheral Vascular and Transcranial for radiological examinations only.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

807.92(a)(6)

Technological Characteristics

The 6200 and 6250 Upgrades employ the same fundamental technological characteristics as their predicate devices.

The 6200 Upgrade model is substantially equivalent to Esaote 6200 model cleared via K133905, Esaote 6400 cleared via K142008, Esaote Europ ART.LAB cleared via K061961, Hitachi Preirus cleared via K093466, and Hitachi Aloka Arietta 70 cleared via K134016.

The 6250 Upgrade model is substantially equivalent to Esaote 6250 model cleared via K133905, Esaote 6400 cleared via K142008, Esaote Europ ART.LAB cleared via K061961, Hitachi Preirus cleared via K093466, and Hitachi Aloka Arietta 70 cleared via K134016.

- Clinical uses for which Esaote 6200 and 6250 models have been cleared via 510(k) K133905 and are not changed by 6200 and 6250 Upgrades, to be cleared via this submission.
- 6200 and 6250 Upgrades for managing Pulsed Wave Doppler probe are equivalent to those of Esaote 6400 model, cleared via K142008.
- 6200 and 6250 Upgrades for managing Quality Artery Stiffness (QAS) are equivalent to eTracking feature of Hitachi Aloka Arietta 70 cleared via K134016 and Esaote ART.LAB software cleared via K061961.
- 6200 and 6250 Upgrades for managing Elastosonography in Abdominal, Intraoperative Abdominal, Transvaginal and Urology applications are equivalent to those of Hitachi Aloka Arietta 70 cleared via K134016 and Hitachi Preirus cleared via K093466.

- 6200 and 6250 Upgrades for managing Elastosonograpy measures is equivalent to those of Hitachi Aloka Arietta 70 cleared via K134016 and Hitachi Preirus cleared via K093466.
- 6200 and 6250 Upgrades for managing STIC with Volumetric Probes is equivalent to STIC feature of Hitachi Aloka Arietta 70 cleared via K134016.
- 6200 and 6250 Upgrades for managing Intraoperative (Neurological) application are equivalent to those of Hitachi Aloka Arietta 70 cleared via K134016.
- Esaote 6200 Upgrade, 6250 Upgrade, 6400, Hitachi Aloka Arietta 70 are designed to meet the IEC60601-1.
- Esaote 6200 Upgrade, 6250 Upgrade, 6400, Hitachi Aloka Arietta 70 are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 6200 Upgrade, 6250 Upgrade, 6400, Hitachi Aloka Arietta 70 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 devices have been evaluated for performance, 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 6060 1-2-37
- 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 6200 and 6250 Upgrades are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.