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

April 1, 2019

Re: K190447
Trade/Device Name: 7400 Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: March 4, 2019
Received: March 5, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190447

Device Name
7400 Ultrasound System

Indications for Use *(Describe)*

Esaote 7400, MyLabOmega, is a compact portable system intended to perform diagnostic general ultrasound studies including: Fetal, Abdominal, Intraoperative (Abdominal), Laparoscopic, Pediatric, Small organs, Neonatal, Neonatal Cephalic, Adult Cephalic, Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Urological, Cardiovascular Adult, Cardiovascular Pediatric, Transoesophageal (cardiac), Peripheral Vessel.

The equipment provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular, or other anatomical structures, as well as peripheral nerve blocks in Musculoskeletal applications.

The ultrasonic medical diagnostic equipment is intended to be connected to mechanical and electronic ultrasound probes (convex array, linear array and phased array) and Doppler probes.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"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."

7400

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	P: 5, 6
Abdominal	P	P	P	P	P	P	P		P	P: 5, 6
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic	P	P	P	P	P	P	P		P	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) [2]	P	P	P	P	P	P	P	P	P	P: 5
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	P	P	P	P	P	P	P		P	P: 5
Laparoscopic	P	P	P		P	P	P		P	P:5
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P	P	P	P	P		P	P: 5 P: 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 K161359 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)

SP2442

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	P: 5
Small Organs [1]										
Neonatal Cephalic	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: 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 K161359

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

SL1543

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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 K161359

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

SL2325

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

	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 K161359

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

SL3116

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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: 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)										

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 K161359

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

AC2541

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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 K161359

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

SC3123

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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]										
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 K161359

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

SI2C41

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

	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
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]										
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 K161359

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

SE3123

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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 K161359

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

SE3133

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

	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	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

Previously cleared via K161359

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

IOT342

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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 K161359

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

IH 6-18

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

	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	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

Previously cleared via K161359

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

IL 4-13

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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)										

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 K161359

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

LP 4-13

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (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										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

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 K161359

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

TLC 3-13

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	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 K161359

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

S2MCW

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

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

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

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

SHFCW

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

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

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

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

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

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

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

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

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

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										
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 P: 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

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

EC1123

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
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)

L 4-15

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	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]										
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 K173291

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

P 1-5

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

	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	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										
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+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 K173291 and to be cleared with this submission for 7400

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

510(k) Summary

K190447

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: March 4, 2019

807.92(a)(2)

Devices

Common Name: Ultrasound Imaging System

Trade Name: 7400 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	K161359	7400 – MyLabAlpha	Esaote S.p.A.
Reference	K173291	6440 – MyLab 9 eXP	Esaote S.p.A.

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

807.92(a)(4)

Device Description

The upgraded 7400 system (MyLabOmega) is 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. Model 7400 manages Qualitative Elastosonography. 7400 is equipped with a LCD color display where acquired images and advanced image features are shown. 7400 can drive Phased, Convex, Linear array, Doppler probes and Volumetric probes (Bi-Scan probes). On both models the touchscreen has an emulation of the Qwerty alphanumeric keyboard that allows data entry. 7400 model is equipped with wireless capability and has been designed to be powered by battery.

7400 has been cleared via k111302, K132231, K132466, K142008 and K161359.

The upgraded 7400 system, defined herein, combines the cleared features of both the 6440 and 7400 systems with new capabilities, listed below:

1. Addition of Auto NT option.
2. Addition of MicroV option.
3. Addition of Qpack option.
4. Management of probe P 1-5.
5. Management of probe L 4-15
6. Addition of 4D Stic option.
7. Addition of Full screen option.
8. Operative system Windows 10

The 7400 new version is manufactured under an ISO 9001 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use

Esaote 7400 is a compact portable system intended to perform diagnostic general ultrasound studies including: Fetal, Abdominal, Intraoperative (Abdominal), Laparoscopic, Pediatric, Small organs, Neonatal, Neonatal Cephalic, Adult Cephalic, Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Urological, Cardiovascular Adult, Cardiovascular Pediatric, Transoesophageal (cardiac), Peripheral Vessel.

The equipment provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular, or other anatomical structures, as well as peripheral nerve blocks in Musculoskeletal applications.

The ultrasonic medical diagnostic equipment is intended to be connected to mechanical and electronic ultrasound probes (convex array, linear array and phased array) and Doppler probes.

807.92(a)(6)

Technological Characteristics

The 7400 upgrade employs the same fundamental technological characteristics as their predicate devices.

The 7400 upgraded system is substantially equivalent to Esaote 7400 model cleared via K111302, and updated via K161359 clearance.

- Clinical uses for which Esaote 7400 and 6440 models have been respectively cleared by FDA via K142008 and K173291 are not changed by the new 6420 version, to be cleared via this submission.
- Auto NT option on the upgraded 7400 system is identical to the one of Esaote 6440 model, cleared via K173291.
- Auto EF (Ejection fraction) option on the upgraded 7400 system is identical to the one of Esaote 6440 model, cleared via K173291.
- Qpack option on the upgraded 7400 system is identical to the one of Esaote 6440 model, cleared via K173291.
- The probe L 4-15 management, added on the upgraded 7400 system has already cleared via K173291.
- The probe P 1-5 management, added on the upgraded 7400 system has already cleared via K173291.
- The upgraded 7400 system offer Full screen mode, identical to the one of Esaote 6440 model, cleared via K173291.
- The upgraded 7400 system works with Windows 10 Enterprise LTSB, operative system, exactly like Esaote 6440 model, cleared via K173291.

807.92(b)(1)

Summary of Non-Clinical Tests

The upgraded 7400 (MyLabOmega) system has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-37
- NEMA UD-3 - Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 - Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The upgraded 7400 system is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.