JUL 2 2 2011

K111302

Traditional 510(k) Summary

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

807.92(a)(1)

Submitter Information

Esaote S.p.A.
Via Siffredi 58
Genoa, Italy 16153

Contact Person: Allison Scott
317.569.9500 x106
ascott@ansongroup.com

Date: May 9, 2011

807.92(a)(2)

Trade Name: 6400 System
7400 System

Common Name: Ultrasound Imaging System

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

Classification Number: 90IYN; 90IYO; 90ITX

807.92(a)(3)

Predicate Device(s)

K050326, K052805 and K060827	7350	Esaote, S.p.A.
K081794 and K091009	7340	Esaote, S.p.A.
K101605	8100	Esaote Europe, B.v.

807.92 (a)(4)

Device Description

6400 is a mainframe system equipped with wheels allowing to move the system. 7400 is a portable system equipped with a handle. The system size and weight allow it to be carried using its handle. The primary modes of operation are: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD) and Tissue Velocity Mapping (TVM). Both 6400 and 7400 are equipped with a LCD color display where acquired images and advanced image features are shown. Both 6400 and 7400 can drive Phased, Convex, Linear array, Doppler probes and Volumetric probes. 6400 control panel is equipped with a pull-out Qwerty alphanumeric keyboard that allows data entry. On 7400 model the touchscreen has an emulation of the Qwerty alphanumeric keyboard that allows data entry. Both 6400 and 7400 systems are equipped with wireless capability. The 6400 and 7400 systems are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 6400 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, and Other: Urologic. The 6400 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 7400 is a compact ultrasound system 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, and Other: Urologic. The 7400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

The 6400 and 7400 systems employ the same fundamental technological characteristics as their predicate devices. The 6400 system is substantially equivalent to the Esaote 7350 cleared by FDA via K050326, K052805 and K060827. The 7400 system is substantially equivalent to the Esaote 7340 cleared by FDA via K081794 and K091009. Both 6400 and 7400 Wi-Fi connectivity is substantially equivalent to the Esaote Europe model 8100 cleared via K101605.

- Clinical uses for which respectively 6400 and 7400 are designed, are equivalent to those cleared for Esaote 7350 and 7340.
- Both 6400 and 7400 are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Both 6400 and 7400 provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.
- Esaote 6400, 7400, 7350 and 7340 systems provide a similar measurements and analysis package.
- Esaote 6400, 7400, 7350 and 7340 systems have digital storage capabilities, including Network connectivity.
- Esaote 7400, designed to be powered by battery, is equivalent to 7340 system, cleared for battery powering via K081794.

807.92(b)(1)

Summary of Non-Clinical Tests

The devices have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 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 6400 and 7400 are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Esaote, S.p.A.
% Ms. Allison Scott
Regulatory Associate
Anson Group
11460 N. Meridian Street, Suite 150
CARMEL IN 46032

JUL 22 2011

Re: K111302
Trade/Device Name: 6400 and 7400 Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 9, 2011
Received: May 9, 2001

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the 6400 and 7400 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

SP2430	S5MCW
LA523	SHFCW
AL2442	SE123
AL2443	TRT33
AC2541	ST2612
S2MCW	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy, Ph.D. at (301) 796-6242.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Models 6400 and 7400

Indications for Use

510(k) Number (if known):

Device Name: 6400 and 7400 Ultrasound Systems

Esaote's Model 6400 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, and Other: Urologic. The 6400 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 7400 is a compact ultrasound system 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, and Other: Urologic. The 7400 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.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111302

6400

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	N	N	N	N	N	N	N		N	5, 6, 9, 10
Abdominal	N	N	N	N	N	N	N		N	5, 6, 9, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	5, 6, 9, 10
Small Organs [1]	N	N	N		N	N	N		N	5, 6, 9, 10
Neonatal Cephalic	N	N	N	N	N	N	N		N	5, 6, 9, 10
Adult Cephalic	N	N	N	N	N	N	N		N	5, 6, 9, 10
Cardiac [2]	N	N	N	N	N	N	N	N	N [11]	5, 6, 7, 8, 9, 10
Transesophageal (Cardiac)	N	N	N	N	N	N	N	N	N	5, 6, 7, 8, 9, 10
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	5, 6, 9, 10
Transvaginal	N	N	N		N	N	N		N	5, 6, 9, 10
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N	N	N	N	N		N	5, 6, 9, 10
Laparoscopic										
Musculo-skeletal Conventional [3]	N	N	N		N	N	N		N	5, 6, 9, 10
Musculo-skeletal Superficial [3]	N	N	N		N	N	N		N	5, 6, 9, 10
Other (Urological)	N	N	N		N	N	N		N	5, 6, 9, 10

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] Compass M-Mode (CMM)
[6] XView
[7] Stress
[8] Xstrain
[9] Compound Imaging (Mview)
[10] Trapezoidal View (TP-View)
[11] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

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

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111302

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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N	N	N	N	N		N	5, 6, 9, 10
Abdominal	N	N	N	N	N	N	N		N	5, 6, 9, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	5, 6, 9, 10
Small Organs [1]	N	N	N		N	N	N		N	5, 6, 9, 10
Neonatal Cephalic	N	N	N	N	N	N	N		N	5, 6, 9, 10
Adult Cephalic	N	N	N	N	N	N	N		N	5, 6, 9, 10
Cardiac [2]	N	N	N	N	N	N	N	N	N [11]	5, 6, 7, 8, 9, 10
Transesophageal (Cardiac)	N	N	N	N	N	N	N	N	N	5, 6, 7, 8, 9, 10
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	5, 6, 9, 10
Transvaginal	N	N	N		N	N	N		N	5, 6, 9, 10
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N	N	N	N	N		N	5, 6, 9, 10
Laparoscopic										
Musculo-skeletal Conventional [3]	N	N	N		N	N	N		N	5, 6, 9, 10
Musculo-skeletal Superficial [3]	N	N	N		N	N	N		N	5, 6, 9, 10
Other (Urological)	N	N	N		N	N	N		N	5, 6, 9, 10

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] Compass M-Mode (CMM)
[6] XView
[7] Stress
[8] Xstrain
[9] Compound Imaging (Mview)
[10] Trapezoidal View (TP-View)
[11] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111302

SP2430

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	N	N	N	N	N	N	N		N	5, 6
Abdominal	N	N	N	N	N	N	N		N	5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N	N	N	N	N		N	5, 6
Small Organs [1]										
Neonatal Cephalic	N	N	N	N	N	N	N		N	5, 6
Adult Cephalic	N	N	N	N	N	N	N		N	5, 6
Cardiac [2]	N	N	N	N	N	N	N	N	N (11)	5, 6, 7, 8
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N	N	N	N	N		N	5, 6
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] Compass M-Mode (CMM)
[6] XView
[7] Stress
[8] Xstrain
[11] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

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

Mary Ann Stoll
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111302

LA523

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	6, 9, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]	P	P	P		P	P	P		P	5, 6, 9, 10
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	6, 7, 8, 9, 10
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 9, 10
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	5, 6, 9, 10
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	5, 6, 9, 10
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] Compass M-Mode (CMM)
[6] XView
[7] Stress
[8] Xstrain
[9] Compound Imaging (Mview)
[10] Trapezoidal View (TP-View)

Previously Cleared via K100931 & K091009

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111302

AL2442

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

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	N	N	N		N	N	N		N	5, 6, 9, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]	N	N	N		N	N	N		N	5, 6, 9, 10
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	N	N	N		N	N	N		N	5, 6, 7, 8, 9, 10
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N		N	5, 6, 9, 10
Laparoscopic										
Musculo-skeletal Conventional [3]	N	N	N		N	N	N		N	5, 6, 9, 10
Musculo-skeletal Superficial [3]	N	N	N		N	N	N		N	5, 6, 9, 10
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] Compass M-Mode (CMM)
[6] XView
[7] Stress
[8] Xstrain
[9] Compound Imaging (Mview)
[10] Trapezoidal View (TP-View)

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Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111302

AL2443

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	N	N	N		N	N	N		N	5, 6, 9, 10
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]	N	N	N		N	N	N		N	5, 6, 9, 10
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	N	N	N		N	N	N		N	5, 6, 7, 8, 9, 10
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N		N	5, 6, 9, 10
Laparoscopic										
Musculo-skeletal Conventional [3]	N	N	N		N	N	N		N	5, 6, 9, 10
Musculo-skeletal Superficial [3]	N	N	N		N	N	N		N	5, 6, 9, 10
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] Compass M-Mode (CMM)
[6] XView
[7] Stress
[8] Xstrain
[9] Compound Imaging (Mview)
[10] Trapezoidal View (TP-View)

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111302

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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 11
Abdominal	N	N	N		N	N	N		N	5, 6, 11
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	N	N	N		N	N	N		N	5, 6, 11
Laparoscopic										
Musculo-skeletal Conventional [3]	N	N	N		N	N	N		N	5, 6, 11
Musculo-skeletal Superficial [3]	N	N	N		N	N	N		N	5, 6, 11
Other (Urological)	N	N	N		N	N	N		N	5, 6, 11

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] Compass M-Mode (CMM)
[6] XView
[9] Compound Imaging (Mview)

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Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111302

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]	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]				N						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				N						
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:

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K 611302

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]	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				N						
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:

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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]	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				N						
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:

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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]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 11
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	5, 6, 11
Transvaginal	N	N	N		N	N	N		N	5, 6, 11
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	N	N	N		N	N	N		N	5, 6, 11

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] Compass M-Mode (CMM)
[6] XView
[9] Compound Imaging (Mview)

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TRT33

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	P	P	P		P	P	P		P	5, 6, 9, 10
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	5, 6, 9, 10

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] Compass M-Mode (CMM)
[6] XView
[9] Compound Imaging (Mview)
[10] Trapezoidal View (TP-View)

Previously Cleared via K110688

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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]	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)	N	N	N	N	N	N	N	N	N	5, 6, 7, 8
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] Compass M-Mode (CMM)
[6] XView
[7] Stress
[8] Xstrain

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