K121384

MAY 23 2012

Special 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 di Caciolle 15
Firenze, Italy 50127

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

Date: May 4, 2012

807.92(a)(2)

Trade Name: 7348 System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse Doppler imaging system 892.1550
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

k081794, k091009, k110688	7340	Esaote, S.p.A.

807.92 (a)(4)

Device Description

The 7340 is a compact ultrasound system, used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping, Amplitude Doppler (AD) and Tissue Enhancement Imaging (TEI). The system is equipped with a LCD Color Display, a control panel and is capable of operating Linear, Convex, and Phased array probes.

The 7340 system has been cleared by FDA via k081794, k091009 and k110688.

The 7340 has been modified from the previously cleared version, in order to add a low-cost configuration, named 7348 (modified 7340). Advanced features (such as Stress, Strain, 3D/4D) are not available in the 7348.

The main changes to model 7340 consist of the following:

a. New plastic housing of the system to give a new style.
b. New keyboard (control panel) where the modality to select software keys has been modified and some control keys have been replaced by software keys.
c. New Keyboard PCB lay out to match the new organization of the panel keys.
d. New Processor PCB group to have two configurations: basic-performance group for 7348 and high-performance group for 7340.
e. Software modifications to translate new organization of the panel keys and to manage the two Processor PCB group configurations; all other software characteristics and performances have not been changed.

The 7348 is equipped with a sub-set of the 7340 probes: the intended use of the probes remains unchanged as previously cleared.

These modifications do not affect the intended use or alter the fundamental scientific technology of the 7340 system cleared via k081794, k091009 and k110688.

807.92(a)(5)

Intended Use(s)

Esaote's Model 7348 is a portable ultrasound system used to perform diagnostic general ultrasound studies including Cardiac (adult and pediatric), Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transrectal, Transvaginal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 7348 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 7340 has been modified from the previously cleared version, in order to add a low-cost configuration, named 7348 (modified 7340). The modifications have altered neither the fundamental scientific technology nor the intended use of the unmodified version of the 7340 cleared via k081794, k091009 and k110688.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Esaote, S.p.A.
% Allison Scott, RAC
Regulatory Associate
Anson Group
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

MAY 23 2012

Re: K121384
Trade/Device Name: 7348 Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name:
Regulatory Class: II
Product Code: IYN and IYO
Dated: May 4, 2012
Received: May 8, 2012

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 7348 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

7348 (Modified 7340)	7348 – LA522	7348 – 5 CW
7348 – PA230	7348 – LA523	7348 – EC1123
7348 – PA122	7348 – CA123	7348 – IOE323
7348 – PA023	7348 – CA431	7348 – LP323
7348 – LA435	7348 – 2 CW	7348 – TEE132

7348 – TEE022

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 Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Model 7348 (Modified 7340)

Indications for Use

Special 510(k) Number (if known):

Device Name: 7348 Ultrasound Systems

Esaote's Model 7348 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac (adult and pediatric), Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transrectal, Transvaginal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 7348 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)

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K121384

7348 (Modified 7340)

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	
Abdominal	P	P	P	P	P	P	P		P	
Intraoperative (Abdominal)	P	P	P		P	P	P		P	
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic	P	P	P	P	P	P	P		P	
Adult Cephalic	P	P	P	P	P	P	P		P	
Cardiac [2]	P	P	P	P	P	P	P		P	
Transesophageal (Cardiac)	P	P	P	P	P	P	P		P	
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	
Transvaginal	P	P	P		P	P	P		P	
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	
Laparoscopic	P	P	P		P	P	P		P	
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)	P	P	P		P	P	P		P	

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

Previously cleared via k081794, k091009 and k110688

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) k121384

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

7348 - PA230

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	
Cardiac [2]	P	P	P	P	P	P	P		P	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

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

510K K121384

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

7348 - PA122

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	Combined [3]	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	
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P		P	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121384

Prescription Use Only Per 21 CFR 801

Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

7348 - PA023

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	Combined [3]	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	
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P		P	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121384

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

7348 - LA435

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P			
Small Organ [1]	P	P	P		P	P	P			
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P			
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P			
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P			
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121384

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

7348 - LA522

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

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Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121384

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

7348 - 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	Combined [3]	Tissue Velocity Mapping	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

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

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121384

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

7348 - CA123

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic	P	P	P		P	P	P		P	
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

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

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

510K K121384

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

7348 - CA431

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	
Abdominal	P	P	P		P	P	P		P	
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [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	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)	P	P	P		P	P	P		P	

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

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(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121384

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

7348 - 2 CW

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	Combined (3)	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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[1] Small Organs includes Breast, Thyroid and Testicles

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(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121384

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

7348 - 5 CW

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121384

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

7348 - 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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	
Transvaginal	P	P	P		P	P	P		P	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CPM + PD

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121384

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

7348 - IOE323

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	
Intraoperative (Abdominal)	P	P	P		P	P	P		P	
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)										

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

Previously cleared via k110688

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

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

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

7348 - LP323

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [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	
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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7348 - TEE132

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P		P	
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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

Previously cleared via k110688

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

510K k121384

Prescription Use Only Per 21 CFR 801

7348 - TEE022

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	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P		P	
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

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

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