K050326

FEB 2 8 2005

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

Carri Graham, Official Correspondent
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250
Phone: (317) 849-1916 x103
Facsimile: (317) 577-9070

Contact Person: Carri Graham

Date: February 4, 2005

807.92(a)(2)

Trade Name: 7350 Ultrasound Imaging 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)

Esaote, S.p.A.	7250 Ultrasound Imaging System	K982444
Esaote, S.p.A.	7250 Ultrasound Imaging System	K994369
Esaote, S.p.A.	7300 Ultrasound Imaging System	K040596

807.92 (a)(4)

Device Description

The 7350 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Doppler and Color Flow Mapping and, on lower frequency probes, Tissue Enhancement Imaging (TEI). The 7350 is equipped with a CRT Color Display. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations. The 7350 can drive phased (PA), convex (CA) and linear array (LA) probes.
The 7350 is equipped with a CD-RW disk drive that can be used for image storage. Data can also be stored directly to a Personal Computer via a LAN port. Optional accessory devices available for the 7350 include an S-VHS video recorder; a monochrome or color page printer. The 7350 is equipped with an isolation transformer to adequately insulate the system's peripherals.

807.92(a)(5)

Intended Use(s)

Esaote's Model 7350 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal and Pediatric.

807.92(a)(6)

Technological Characteristics

	7350 (This submission)	7300 (K040596)	Megas (K982444 & 994369)
Electrical Safety	IEC60601-1	IEC60601-1	IEC60601-1
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)
Indication for Use			
• Cardiac	YES	YES	YES
• Transesophageal	YES	YES	YES
• Peripheral Vascular	YES	YES	YES
• Neonatal Cephalic	YES	YES	YES
• Adult Cephalic	YES	YES	YES
• Small organ	YES	YES	YES
• Musculoskeletal (conventional & superficial)	YES	**YES**	NO
• Abdominal	YES	YES	YES
OB/Fetal	YES	YES	YES
• Transvaginal	YES	YES	YES
• Transrectal	YES	YES	YES
• Pediatric	YES	YES	YES
Probe Technology			
• Phased Array	YES	YES	YES
• Linear Array	YES	YES	YES
• Convex Array	YES	YES	YES
▪			
▪ Doppler Probes	YES	YES	YES
Modes of operation	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI
Imaging Frequencies	2.0,2.5, 3.5, 5.0, 7.5, 10 MHz	2.0,2.5, 3.5, 5.0, 7.5, 10 MHz	2.0,2.5, 3.5, 5.0, 7.5, 10 MHz
CFM/Doppler Frequencies	2.0, 2.5, 3.3, 5.0, 6.6, 8.0 MHz	2.0, 2.5, 3.3, 5.0, 6.6 MHz	2.0, 2.5, 3.3, 5.0 MHz
Tissue Velocity Mapping feature	YES	YES	NO
Biopsy Guidance	YES	YES	YES
• Biopsy Intended Uses	General Purpose, Transrectal, Transvaginal	General Purpose, Transrectal, Transvaginal	General Purpose, Transrectal, Transvaginal
• Biopsy Line Depth marker	1 cm	1 cm	1 cm
Needle Guide Angle	ABS421: 20° 30° ABS523: 45° ABS123: 3.8°	ABS421: 20° 30° ABS523: 45° ABS123: 3.8°	ABS421: 20° 30° ABS523: 45° ABS123: 3.8°

	7350 (This submission)	**7300 (K040596)**	**Megas (K982444 & 994369)**
	ABS621: 25° 35°	ABS621: 25° 35°	ABS621: 25° 35°
Display type	CRT	LCD	LCD or CRT (optional)
Display Standard	SVGA	SVGA	SVGA
Digital Archival Capabilities	YES	YES	YES
DICOM Classes: Media Storage, Storage SCU	YES	YES	YES
VCR / Page Printer	YES	YES	YES
M&A Capabilities	Cardiac, Vascular, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements
Weight	90 kg	portable: 10 kg with trolley: 40 kg	25 kg
Dimensions	60(w) x 155(h) x 90(d) cm	portable position: 35.5 (w) x 14 (h) x 49 (d) cm use position: 35.5 (w) x 41 (h) x 49 (d) cm with trolley: 50 (w) x 130 (h) x 51 (d) cm	portable position: 46 (w) x 23.5 (h) x 55 (d) cm use position: 46 (w) x 23.5 (h) x 68 (d) cm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2005

Esaote S.p.A.
% Ms. Carri Graham
The Anson Group
7992 Castleway Drive
INDIANAPLOIS IN 46250

Re: K050326
Trade Name: 7350 Ultrasound Imaging System (or MyLab50)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: February 4, 2005
Received: February 9, 2005

Dear Ms. Graham:

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 7350 Ultrasound Imaging System (or MyLab50), as described in your premarket notification:

Transducer Model Number

PA230	PA023
PA121	LA522
PA122	LA532

LA523	CA123
LA424	2.0 CW
CA421	5.0 CW
CA430	EC123
CA621	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 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); 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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small

Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html
If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Mod.7350

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N [1]	N [3]
Abdominal		N	N	N		N	N		N [1]	N [3]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N [1]	N [3]
Small Organ (specify) [2]		N	N	N	N	N	N		N [1]	N [3]
Neonatal Cephalic		N	N	N	N	N	N		N [1]	
Adult Cephalic										
Cardiac		N	N	N	N	N			N [1]	N [3]
Transesophageal		N	N	N	N	N			N [1]	
Transrectal		N	N	N		N	N		N [1]	
Transvaginal		N	N	N		N	N		N [1]	
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N [1]	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N	N	N	N		N [1]	
Musculo-skeletal Superficial		N	N	N	N	N	N		N [1]	
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW+CW+CFM+PD

[2] Small organs include Thyroid, Breast and Testicles.

[3] Tissue Harmonic Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hegarman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050326

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA230**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		N [1]	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N [1]	N [3]
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW+CW+CFM+PD

[3] Tissue Harmonic Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hanson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050326

PA121

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		N [1]	N [3]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N			N [1]	N [3]
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
[1] Applicable combined modes: B+PW+CFM+M+PD
[3] Tissue Harmonic Imaging

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050326

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA122**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N[1]	
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N[1]	
Adult Cephalic										
Cardiac		N	N	N	N	N			N[1]	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N[1]	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW+CW+CFM+PD

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hoom

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050326

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N [1]	
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N [1]	
Adult Cephalic										
Cardiac		N	N	N	N	N			N [1]	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N [1]	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
[1] Applicable combined modes: B+PW+CFM+M+PD

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K050326

Prescription Use ✓

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N [1]	
Small Organ (specify) [2]		N	N	N		N	N		N [1]	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N [1]	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
[1] Applicable combined modes: B+PW+CFM+M+PD
[2] Small Organs (specifically, thyroid, testicles, and breast)_

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050326

Prescription Use

LA532

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N [1]	
Small Organ (specify) [2]		N	N	N	N	N	N		N [1]	N [3]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N [1]	N [3]
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
[1] Applicable combined modes: B+PW+CFM+M+PD
[2] Small Organs (specifically, thyroid, testicles, and breast);
[3] Tissue Harmonic Imaging

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050326

Diagnostic Ultrasound Indications for Use Form

Transducer: **LA523**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[1]	
Small Organ (specify) [2]		N	N	N		N	N		N[1]	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[1]	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N[1]	
Musculo-skeletal Superficial		N	N	N		N	N		N[1]	
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW+CW+CFM+PD

[2] Small organs include Thyroid, Breast and Testicles.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(K) Number K050326

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N [1]	
Small Organ (specify) [2]		N	N	N		N	N		N [1]	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N [1]	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N [1]	
Musculo-skeletal Superficial		N	N	N		N	N		N [1]	
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
[1] Applicable combined modes: B+PW+CFM+M+PD
[2] Small Organs (specifically, thyroid, testicles, and breast)_

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,

Diagnostic Ultrasound Indications for Use Form

Transducer: **CA421**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N[1]	N[3]
Abdominal		N	N	N		N	N		N[1]	N[3]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N [1]	N [3]
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[1]	N[3]
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW+CFM+PD.

[3] Tissue Harmonic Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Ingram

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) number K050326

CA430

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		N [1]	
Abdominal		N	N	N	N	N	N		N [1]	N [3]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N [1]	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
[1] Applicable combined modes: B+PW+CFM+M+PD
[3] Tissue Harmonic Imaging

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerla

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K050326

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N [1]	N [3]
Abdominal		N	N	N		N	N		N [1]	N [3]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N [1]	N [3]
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
[1] Applicable combined modes: B+PW+CFM+M+PD
[3] Tissue Enhanced Imaging (TEI)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K150326

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N [1]	
Small Organ (specify) [2]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N [1]	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N [1]	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

[1] Applicable combined modes: B+PW+CFM+M+PD

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050326

2.0 CW

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K050326

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

Diagnostic Ultrasound Indications for Use Form

Transducer: **EC123**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		N[1]	
Transvaginal		N	N	N		N	N		N[1]	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW+CFM+PD.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050326

Diagnostic Ultrasound Indications for Use Form

Transducer: **TEE022**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac									N[1]	
Transesophageal		N	N	N	N	N				
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW++CW+CFM+PD

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050326