K051837

JUL 20 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: June 24, 2005

807.92(a)(2)

Trade Name: (6100) MyLab90 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.	7350 Ultrasound Imaging System	K050326
Esaote, S.p.A.	Technos Ultrasound Imaging System	K990360
Esaote, S.p.A.	Technos Ultrasound Imaging System	K014168
Esaote, S.p.A.	Technos Ultrasound Imaging System	K023255
Phillips, Inc.	iU22 Ultrasound Imaging System	K042540

807.92 (a)(4)

Device Description

The 6100 MyLab 90 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 6100 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 6100 can drive phased (PA), convex (CA), linear array (LA) and Doppler probes.
The 6100 is equipped with a DVD-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 6100 include an S-VHS video recorder; a monochrome or color page printer. The 6100 is equipped with an isolation transformer to adequately insulate the system's peripherals.

807.92(a)(5)

Intended Use(s)

Esaote's MyLab90 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, Adult Cephalic, Pediatric, Laparoscopic, Intraoperative: Abdominal, and Other: Urologic.

807.92(a)(6)

Technological Characteristics

	6100 MyLab 90 this submission	Technos (K990360, K014168 & K023255) Esaote, S.p.A.	7350 MyLab 50 (K050326) Esaote, S.p.A.	Megas (K982444) Esaote, S.p.A.	iU22 by Philips (K042540) Philips
Electrical Safety	IEC60601-1	IEC60601-1	IEC60601-1	IEC60601-1	IEC60601-1
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)
Indication for Use					
• OB/Fetal	YES	YES	YES	YES	YES
• Abdominal	YES	YES	YES	YES	YES
• Intraoperative: Abdominal	YES	YES	NO	NO	YES
• Pediatric	YES	YES	YES	YES	YES
• Small organ	YES	YES	YES	YES	YES
• Neonatal Cephalic	YES	YES	YES	YES	YES
• Adult Cephalic	YES	YES	YES	YES	YES
• Cardiac	YES	YES	YES	YES	YES
• Transesophageal	YES	YES	YES	YES	YES
• Transrectal	YES	YES	YES	YES	YES
• Transvaginal	YES	YES	YES	YES	YES
• Peripheral Vascular	YES	YES	YES	YES	YES
• Laparoscopic	YES	YES	NO	NO	YES
• Musculoskeletal (conventional & superficial)	YES	YES	YES	NO	YES
• Other: Urological	YES	YES	NO	NO	YES
Probe Technology					
• Phased Array	YES	YES	YES	YES	N/A
• Linear Array	YES	YES	YES	YES	YES
• Convex Array	YES	YES	YES	YES	YES
• Doppler Probes	YES	YES	YES	YES	YES
• Bi-Scan	YES	NO	NO	YES	N/A

	6100 MyLab 90 this submission	Technos (K990360, K014168 & K023255) Esaote, S.p.A.	7350 MyLab 50 (K050326) Esaote, S.p.A	Megas (K982444) Esaote, S.p.A.	iU22 by Philips (K042540) Philips
Modes of operation					
2D, M-Mode, PW, CW, CFM, Amplitude Doppler (PD), TEI	YES	YES	YES	YES	YES
CnTI	YES	YES	YES	NO	YES
TVM	YES	YES	YES	NO	YES
VPAN	YES	YES	NO	NO	YES
Compound Imaging	YES	NO	NO	NO	YES
3D	YES	YES	NO	NO	YES
Imaging Frequencies	1 - 16 MHz	1.5 - 16 MHz	2 - 10 MHz	2 - 10 MHz	N/A
CFM/Doppler Frequencies	2 - 12 MHz	2 - 12 MHz	2 - 8 MHz	2 - -5 MHz	N/A
Tissue Velocity Mapping feature	YES	YES	YES	NO	NO
Intelligent Real-Time Image Processing	YES	NO	NO	NO	YES
Biopsy Guidance					
• Biopsy Intended Uses	General Purpose, Transrectal, Transvaginal	General Purpose, Transrectal, Transvaginal	General Purpose, Transrectal, Transvaginal	General Purpose, Transrectal, Transvaginal	N/A
Display type	CRT	CRT	CRT	LCD or CRT (optional)	LCD
Display Standard	SVGA	SVGA	SVGA	SVGA	N/A
Digital Archival Capabilities	YES	YES	YES	YES	YES
DICOM Classes:	Media Storage, Storage SCU	Media Storage, Storage SCU	Media Storage, Storage SCU	Media Storage, Storage SCU	N/A
VCR / Page Printer	YES	YES	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	Cardiac, Vascular, OB and general purpose measurements	N/A
Weight	120 kg	140 kg	90 kg	79 kg	N/A
Dimensions	60(w) x 160(h) x 120(d) cm	60(w) x 160(h) x 105(d) cm	60(w) x 155(h) x 90(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	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2005

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

Re: K051837
Trade Name: MyLab 90 Ultrasound Imaging Systems, Model 6100
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: IYN, IYO, and ITX
Dated: July 5, 2005
Received: July 6, 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 MyLab 90 Ultrasound Imaging Systems, Model 6100, as described in your premarket notification:

Transducer Model Number

BS230	LA532
CA123	LP323
CA421	PA023
CA430	PA121
CA621	PA122
EC123	PA230
IOE323	TEE022
LA424	TRT23
LA522	2 CW
LA523	5CW

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/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

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

Enclosure(s)

Mod. 6100

K051837

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

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

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy
Intraoperative (Abdominal)

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

BS230

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

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

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

CA123

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

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

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI/C³-Mode (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓

CA421

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

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

Additional Comments:
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓

CA430

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

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

Additional Comments:
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

CA621

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

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

Additional Comments:
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051831

Prescription Use ✓

EC123

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

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

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓

IOE323

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

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

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy
Intraoperative (Abdominal)

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051831

Prescription Use ✓

LA424

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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 (see Note 1)	N (see Note 2)
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Muscolo-skeletal Superficial		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Other (Urological)										

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

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

LA522

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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 (see Note 1)	N (see Note 2)
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Muscolo-skeletal Superficial		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Other (Urological)										

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

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

LA523

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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 (see Note 1)	N (see Note 2)
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Muscolo-skeletal Superficial		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Other (Urological)										

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

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓

LA532

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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 (see Note 1)	N (see Note 2)
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

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

(510(k) Number K051837

Prescription Use ✓

LP323

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Description Use ✓

PA023

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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 (see Note 1)	N (see Note 2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

Additional Comments:
Peripheral Vascular to include Vein Mapping & Sclerotherapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

PA121

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

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

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

PA122

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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 (see Note 1)	N (see Note 2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

Additional Comments:
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓

PA230

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

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

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051837

Prescription Use ✓

TEE022

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Transesophageal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓

TRT23

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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										
Transesophageal										
Transrectal		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)		N	N	N		N	N		N (see Note 1)	N (see Note 2)

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

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
Compound

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use /

2 CW

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓

5 CW

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	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										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

Additional Comments:
Peripheral Vascular to include Vein Mapping & Scleroterapy

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051837

Prescription Use ✓