K050326

510(k) Summary 7350 Ultrasound Imaging System Esaote, S.p.A.

## 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:	Febru	ary 4, 2005	
<u>807.92(a)(2)</u>			
Trade Name:	7350	Ultrasound Imaging System	
Common Name:	Ultras	sound Imaging System	
Classification Name	e(s):	Ultrasonic pulse doppler imaging s Ultrasonic pulsed echo imaging sy	
Classification Num	ber:	90IYN; 90IYO	
<u>807.92(a)(3)</u>		Predicate Device(s)	
Esaote, S.p.	4.	7250 Ultrasound Imaging System	K982444
Esaote, S.p.	4.	7250 Ultrasound Imaging System	K994369
Esaote, S.p.	A.	7300 Ultrasound Imaging	K040596

System

510(k) Summary 7350 Ultrasound Imaging System Esaote, S.p.A.

### 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.

<u>807.92(a)(5)</u>

### 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.

### <u>807.92(a)(6)</u>

# **Technological Characteristics**

	7350 (This submission)	7300 (K040596)	Megas (K982444 & 994369)
	IEC60601-1	IEC60601-1	IEC60601-1
Electrical Safety		Track 3 (Acoustic Output	Track 3 (Acoustic Output
Ultrasound Safety	Display)	Display)	Display)
Indication for Use			
Cardiac	YES	YES	YES
	YES	YES	YES
	YES	YES	YES
	YES	YES	YES
Neonatal Cephalic	YES	YES	YES
Adult Cephalic	YES	YES	YES
Small organ	YES	YES	NO
Musculoskeletal	1E3		
(conventional &			
superficial)	YES	YES	YES
Abdominal	YES	YES	YES
OB/Fetal	YES	YES	YES
<ul> <li>Transvaginal</li> </ul>		YES	YES
Transrectal	YES	YES	YES
Pediatric	YES	1123	
Probe Technology		YES	YES
Phased Array	YES	·····	YES
Linear Array	YES	YES	
Convex Array	YES	YES	YES
<ul> <li>Doppler Probes</li> </ul>	YES	YES	YES
Modes of operation	2D, M-Mode, PW, CW, CFM,	2D, M-Mode, PW, CW, CFM,	
	Amplitude Doppler, TEl	Amplitude Doppler, TEI	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
CEM/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	YES	YES	NO
feature			
Biopsy Guidance	YES	YES	YES
Biopsy Intended Uses	General Purpose, Transrectal,	General Purpose, Transrectal,	General Purpose,
- Diopsy intended ober	Transvaginal	Transvaginal	Transrectal, Transvaginal
<ul> <li>Biopsy Line Depth marker</li> </ul>	1 cm	1 cm	1 cm
leedie Guide Angle	ABS421: 20° 30°	ABS421: 20° 30°	ABS421: 20° 30°
vouie Guide / Ingle	ABS523: 45°	ABS523: 45°	ABS523: 45°
	ABS123: 3.8°	ABS123: 3.8°	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	YES	YES	YES
Capabilities DICOM Classes:	YES	YES	YES
Media Storage, Storage			
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



FEB 2 8 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

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
<u>PA122</u>	<u>LA532</u>

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LA523	<u>CA123</u>
	<u>2.0 CW</u>
LA424 CA421	<u>5.0 CW</u>
<u>CA421</u> CA420	EC123
<u>CA430</u>	TEE022
<u>CA621</u>	

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 <u>Federal Register</u>.

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

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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,

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

Enclosure(s)

#### Mod.7350

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

Intended Ose. Diagnostie	Mode of Operation											
Clinical Application	A	в	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetai		N	N	N	ļ	N	N		N [1]	N [3]		
Abdominal	 	N	N	N		N	N		<u>N[1]</u>	_N [3]		
Intraoperative (specify)	_	<u> </u>										
Intraoperative Neurological	_			╞──								
Pediatric		N	N	N	<u>N</u>	<u> </u>	<u>N</u>			N [3]		
Small Organ (specify) [2]		N	N	N	N	N	N		N [1]	N [3]		
Neonatal Cephalic	-	N	N	N	N	<u>N</u>	N		<u> </u>			
Adult Cephalic	+	┨							N [1]	N [3]		
Cardiac	-	N	N_	N	<u>N</u>	<u>N</u>						
Transesophageal	1_	N	N	<u> </u>	N	<u>N</u>			N [1]	<u> </u>		
Transrectal		N	N	<u>N</u>		N	<u>N</u>		<u> </u>			
Transvaginal		N	N	<u> </u>	<u> </u>	<u>N</u>	<u>N</u>		<u>  N [1]</u>			
Transurethral					<u>  </u>					+		
Intravascular			<u> </u>		<u> </u>					+		
Peripheral Vascular		N	N	<u> </u>	<u> </u>	<u>N</u>	<u>N</u>		<u> </u>			
Laparoscopic	1-		1		<u> </u>					+		
Musculo-skeletal Conventional		N	N	N	N	N	N		N [1]			
Musculo-skeletal Superficial		N	N	N	N	<u> </u>	<u>N</u>		<u> </u>			
Other (specify)												

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

Additional Comments:

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

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

[3] Tissue Harmonic Imaging

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### Transducer: PA230

Intended Use: Diagnostic	ultra	asou	nd im	aging o	r fluid fl	ow analysis	s of the huma	n bouy as it		
Intended Use, Diagnostie						<u>M</u>	ode of Operation	<u>m</u>		
Clinical Application	٨	в	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic					\ 	+			+	
Fetal			ļ	<b></b>			┼╌╌╌			
Abdominal		N	<u> </u>	<u>N</u>	<u>N</u>	<u>N</u>	<u>N</u>		<u>N[1]</u>	
Intraoperative (specify)	<u> </u>	ļ	<b> </b>	┨───			+	+		
Intraoperative Neurological	↓_	ļ	<b>↓</b>							
Pediatric	-	<u> </u>	_			- <del> </del>		+		
Small Organ (specify)			┨							
Neonatal Cephalic			┨						_	1
Adult Cephalic	-				┿──		- <u> </u>		N[I]	N [3]
Cardiac	-	<u>N</u>	N	- <u>N</u>	<u>  N</u>	<u></u>	N			+
Transesophageal										
Transrectal	+				+					1
Transvaginal	4-	4—			+					+
Transurethral										
Intravascular	_		_			_{				
Peripheral Vascular	_				_					
Laparoscopic	_+									
Musculo-skeletal Conventional				=						
Musculoskeletal Superficial		1-			_+					
Other (specify)		<u> </u>								!

### but the Discussion ultrasound imaging or fluid flow analysis of the human body as follows:

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

Additional Comments:

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

[3] Tissue Harmonic Imaging

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### Appendix F

#### 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	Α	в	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
)phthalmic												
Fetal	+									N [3]		
Abdominal	┼─	N	N	N		N	N		N [1]			
Intraoperative (specify)					 	 						
Intraoperative Neurological		<u>↓</u>	]									
Pediatric Small Organ (specify) Neonatal Cephalic	_ <del>}</del> _ _ <del>\</del> _	+										
Adult Cephalic				N	N	N			N [1]	N [3]		
Cardiac		N	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:

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

[3] Tissue Harmonic Imaging

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and Radiological Devices	10
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### Transducer: PA122

Intended Use: Diagnostic u	iltra	isout	nd im	aging 0	r fluid fl	ow analyst	s of the numa				
Intended eser 2 4 B	Iltrasound imaging or fluid flow analysis of the human body as follows. <u>Mode of Operation</u>										
Clinical Application	A	в	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic						+					
Fetal				┨────		+					
Abdominal				<b>↓_</b>	<u> </u>	-+	+				
Intraoperative (specify)	<b> </b>		<u> </u>	╂	┼───			+			
Intraoperative Neurological		↓	<b> </b>		╂───		+	+	N[1]		
Pediatric	1_	N	N_	N	N	N	<u>N</u>			1	
Small Organ (specify)	1_										
Neonatal Cephalic		N	N	<u>N</u>	<u>N</u>	<u> </u>	N	-+		1	
Adult Cephalic	1_	1_									
Cardiac	1_	N	<u> </u> N	<u></u>	<u>N</u>	<u> </u>					
Transesophageal		1_									
Transrectal											
Transvaginal											
Transurethral						_					
Intravascular									N[1]		
Peripheral Vascular		1	<u>  N</u>	<u> N</u>	_ <u>N</u> _	N	<u> </u>				
Laparoscopic								_+			
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	-	_+-		_+	_+						
Other (specify)								!	l		

fluid flow analysis of the human body as follows:

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

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#### Appendix F

## 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	В	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic			_								
Fetal	┼┥		<b>_</b>								
Abdominal			<u>.,                                     </u>								
Intraoperative (specify)											
Intraoperative Neurological									N [1]	<u> </u>	
Pediatric		N	N	N	N	N	N	<u> </u>			
Small Organ (specify)					N	N	N		N [1]		
Neonatal Cephalic	1	N	N	N			R				
Adult Cephalic									N [1]		
Cardiac		N	N	N	N	N					
Tranesophageal		+									
Transrectal								<u> </u>			
Transvaginal											
Transurethral			+								
Intravascular		-		1							
Peripheral Vascular		N	N	N	N	N	N		N [1]		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											

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

Additional Comments:

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

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#### Appendix F

#### LA522

### 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	В	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic						2						
Fetal												
Abdominal						<u>}</u>						
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric		N	N	N		N	N	<u>                                     </u>	N [1]	<b> </b>		
Small Organ (specify) [2]		N	N	N	 	N	N		N [1]			
Neonatal Cephalic				<u> </u>		<u> </u>			<u> </u>			
Adult Cephalic												
Cardiac												
Tranesophageal	1-	<u>+</u>										
Transrectal	1	1	1	1								
Transvaginal												
Transurethral						+						
Intravascular			1	- <u> </u>								
Peripheral Vascular		N	N	N		N	N		N [1]			
Laparoscopic												
Musculo-skeletal Conventional		-		-								
Musculo-skeletal Superficial			ļ						_			
Other			<u> </u>			_1				k		

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)\_

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#### AppendixF

## 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	В	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic				<u> </u>		<b> </b>		<u> </u>	<b>_</b>			
Fetal						<u> </u>		 	<b> </b>	+		
Abdominal			1				 		 			
Intraoperative (specify)						<u> </u>		 				
Intraoperative								1				
Neurological		N	N N	+	N	N	N		N [1]			
Small Organ (specify) [2]		N	N	N	N	N _	N		N [1]	N [3]		
Neonatal Cephalic	1-	[					<u> </u>					
Adult Cephalic		<b>∤</b> − 	-									
Cardiac		1										
Tranesophageal		+	+		1							
Transrectal		1										
Transvaginal		1-										
Transurethral			1									
Intrayascular		+	-									
Peripheral Vascular		N	N	N	N	N	N		N [1]	N [3]		
Laparoscopic				ţ								
Musculo-skeletal Conventional									-			
Musculo-skeletal Superficial		_										
Other						!			<b>I</b>			

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

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#### Transducer: LA523

	ultrasound imaging or fluid flow analysis of the numan body us follows. <u>Mode of Operation</u>										
Clinical Application	А	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify	
Ophthalmic				ļ		<u> </u>					
Fetal				<u> </u>	<b> </b>						
Abdominal	<b>_</b>		 	<b> </b>		┧					
Intraoperative (specify)				<u> </u>							
Intraoperative Neurological		<b> </b> -									
Pediatric	<u> </u>	Ν	N	N	<b>↓</b>	N	<u>N</u>		N[1]		
Small Organ (specify) [2]	<u> </u>	Ν	N_	<u>N</u>		<u>N</u>	<u>N</u>	·	N[1]		
Neonatal Cephalic	1-	<u> </u>	<u> </u>		<u> </u>						
Adult Cephalic	╞		<u> </u>	₋	<u> </u>					<u> </u>	
Cardiac	-			<u> </u>	<u> </u>						
Transesophageal		ļ	<u> </u>	╡	<u> </u>						
Transrectal		<u> </u>	<u> </u>		┦───						
Transvaginal		<u> </u>			₋					<u> </u>	
Transurethral		1									
Intravascular	_	1_									
Peripheral Vascular		N	<u>N</u>	N		N	<u>N</u>		<u> </u>		
Laparoscopic	1.	<u> </u>	<u> </u>								
Musculo-skeletal Conventional		И	N	N		N	N		N[1]		
Musculo-skeletal Superficial		N	N	N		N	N		[1]M		
Other (specify)											

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

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.

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### 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	В	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic										l.		
Fetal	+											
Abdominal			+					<u> </u>		1		
Intraoperative (specify)	<u> </u>											
Intraoperative Neurological			1									
Pediatric		N	N	N		N	N		N [1]	ļ		
Small Organ (specify) [2]		N	N	N		N	N		N [1]			
Neonatal Cephalic				1				l				
Adult Cephalic	1			-								
Cardiac	-	1										
Tranesophageal			<u> </u>	-								
Transrectal	+											
Transvaginal												
Transurethral		<u> </u>		-						+		
Intravascular	_	1	+	-	1	1						
Peripheral Vascular Laparoscopic		N	N	N		N	N		N [1]			
				_ <u>_</u>	<u> </u>		N		N [1]			
Musculo-skeletal Conventional		N	N	N		N						
Musculo-skeletal Superficial		N	N	N	<u> </u>	N	N		N [1]			
Other			1		1		<u> </u>		1			

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)\_

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#### Transducer: CA421

Intended Use: Diagnostic	Mode of Operation											
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify		
Ophthalmic						1		<u> </u>				
Fctal		<u>м</u>	N	N	<u> </u>	N	N	<u> </u>	<u> </u>	N[3]		
Abdominal		N	N	<u>N</u>	ļ	N	<u>N</u>		<u>[1]</u>	N[3]		
Intraoperative (specify)	1_	ļ	ļ	ļ				<u> </u>				
Intraoperative Neurological	_	<u> </u>	┨	ļ	ļ_,				_			
Pediatric		N	N	N	ļ	N	N	<u> </u>	<u> </u>	[3] N		
Small Organ (specify)			<u> </u>	<u> </u>	<b>_</b>							
Neonatal Cephalic	1_		<u> </u>	<u> </u>	┨			-				
Adult Cephalic	-			<u> </u>	<b> </b>		_					
Cardiac	┦	<u> </u>			<u> -</u>					+		
Transesophageal		<u> </u>										
Transrectal		<u> </u>	<u> </u>			_						
Transvaginal		1_	<u> </u>		<b>_</b>							
Transurethral				_						1		
Intravascular	_	_										
Peripheral Vascular		N	N	N	<u> </u>	<u>N</u>	N		N[1]	N[3]		
Laparoscopic			_	<u> </u>								
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												

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

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

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#### AppendixF

## 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 o	f Operation			
linical Application	A	В	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	1						N		N [1]	<u> </u>
Fetal		N	N	N	N			 	N [1]	N [3]
Abdominal		N	N	N	N	N	N	 		
Intraoperative (specify)	$\frac{1}{1}$							<u> </u>		
Intraoperative Neurological							<u> </u>			
Pediatric						+				
Small Organ (specify)										-
Neonatal Cephalic						-+				
Adult Cephalic									_	
Cardiac										
Tranesophageal										
Transrectal	-†-									
Transvaginal										
Transurethral	-+-	-+								
Intravascular									N [1]	
Peripheral Vascular		N	I N	N	N	N	N			
Laparoscopic					ł					
Musculo-skeletal Conventional	 									
Musculo-skeletal Superficial										
Other		L				l				

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

Additional Comments:

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

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[3] Tissue Harmonic Imaging

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## 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	В	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal	4	N	N	N		N	N		N [1]	N [3]			
Abdominal		N	N	N		N	N		N [1]	N [3]			
Intraoperative (specify)													
Intraoperative Neurological								 		ļ			
Pediatric			ļ		<u> </u>					<u> </u>			
Small Organ (specify)													
Neonatal Cephalic		1						<u> </u>		<u> </u>			
Adult Cephalic								<u> </u>		_			
Cardiac													
Trancsophageal					1								
Transrectal													
Transvaginal													
Transurethral						-							
Intravascular													
Peripheral Vascular		N	N	N		N	N		N [1]	N [3]			
Laparoscopic													
Musculo-skeletal Conventional Musculo-skeletal						_		<u> </u>					
Superficial													

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)

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## 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	<b>A</b>	В	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal												
Abdominal			+									
Intraoperative (specify)												
Intraoperative Neurological									NIL	- <u> </u>		
Pediatric		N	N	N	N	N	N	<u> </u>	N [1]	<u> </u>		
Small Organ (specify) [2] Neonatal Cephalic	_									<u> </u>		
Adult Cephalic	+-	+	+	-								
Cardiac	_	N	N	N	N	N	N		N [1]			
Tranesophageal	-+		+	-								
Transrectal	_{	+										
Transvaginal												
Transurethral												
Intravascular				1						1		
Peripheral Vascular		N	N	N	N	N	N		N [1]			
Laparoscopic		1										
Musculo-skeletal Conventional				_								
Musculo-skeletal Superficial												
Other					_1			_L	<u> </u>	_1		

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

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

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### AppendixF

## 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	М	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal	1						<u></u>	 		
Abdominal	1						<u> </u>			+
Intraoperative (specify)										 
Intraoperative Neurological							<u> </u>			
Pediatric		<u> </u>	. <b> </b>		╂───	+	+			
Small Organ (specify)		 			<u> </u>					
Neonatal Cephalic		1						<u>  </u>		
Adult Cephalic									<u> </u>	
Cardiac					N					
Tranesophageal	-									
Transrectal										
Transvaginal										
Transurethral		+-								
Intravascular		-								
Peripheral Vascular									_	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										_

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

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Additional Comments:

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#### AppendixF

## 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	В	м	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal			<u>+</u>									
Abdominal			<u> </u>	1								
Intraoperative (specify)	+											
Intraoperative Neurological								·		 		
Pediatric			<u> </u>									
Small Organ (specify)			<u> </u>			<u> </u>						
Neonatal Cephalic		1				1				<u> </u>		
Adult Cephalic												
Cardiac												
Tranesophageal												
Transrectal	-	1										
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:

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### Transducer: EC123

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Intended Use. Diagnostie						<u>M</u>	ode of Operatio	<u>90</u> 			
Clinical Application	A	в	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic								+			
Fetal				┨	┨	+					
Abdominal	_	┨		╂	<u> </u>		+				
Intraoperative (specify)	<u> </u>	<u> </u>	┨		┼╾╾╸		+				
Intraoperative Neurological		┨	┼╌		+						
Pediatric	╁╴	┨	╂─		+						
Small Organ (specify)		+								<u></u>	
Neonatal Cephalic	+-	┼─	╂		+						
Adult Cephalic		+	+	+							
Cardiac		+-	-+-								
Transesophageal	+						N		N[1]		
Transrectal	$\downarrow$	<u> </u> N		<u> </u>			- <u>N</u>		 N[1]		
Transvaginal	_	N			_+	<u> </u>					
Transurethral	_		_+-					- <u>+</u>			
Intravascular	_				-+						
Peripheral Vascular		_									
Laparoscopic		$\rightarrow$	_	_+							
Musculo-skeletal		-+-	<del> </del> _								
Conventional			_+								
Musculoskeletal Superficial		┝╌┠╴	-+								
Other (specify)	_							<u></u>			

timesing or fluid flow analysis of the human body as follows:

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

Additional Comments:

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

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Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as fol Mode of Operation									
Intended Use: Diagnostic	c ult	asou			n nulu i	M	1		
Clinical Application	A	[	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)
			┼	┼	╂╼╼╼╼				_
Ophthalmic		┼─		┼╼──	1				
Fetal	-+-	╂──	+	+					
Abdominal Intraoperative (specify)	-†-								
Intraoperative (specify)	-+-	Τ_		1					╾╾┨──────

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### Transducer: TEE022

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

Additional Comments:

Musculoskeletal Superficial

Pediatric

Intraoperative Neurological

Small Organ (specify) Neonatal Cephalic Adult Cephalic Cardiac

Transesophageal Transrectal Transvaginal Transurethral Intravascular

Peripheral Vascular Laparoscopic Musculo-skeletal Conventional

Other (specify)

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

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Prescription Use (Per 21 CFR 801.109)

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Other (specify)

N[1]