K070903

510(k) Summary

JUL - 2 2007

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham, Official Correspondent
11460 N. Meridian St., Suite 150
Carmel, IN 46032
Phone: (317) 569-9500, extension 103
Facsimile: (317) 569-9520

Contact Person: Carri Graham

Date: March 20, 2007

807.92(a)(2)

Trade Name:	MyLab40 Ultrasound System	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed echo imaging system	892.1560
	Ultrasonic pulsed Doppler imaging system	832.1550
	Diagnostic ultrasonic transducer	892.1570
Classification Number:	IYO	
	IYN	
	ITX	

807.92(a)(3)

Predicate Device(s)

Pie Medical	MyLab20	K043588
Pie Medical	MyLab20	K053154
Esaote Europe	MyLab20	K061755
Esaote S.p.A.	MyLab30	K040596
Esaote S.p.A.	MyLab30	K052805
Esaote S.p.A.	MyLab30	K060827

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

807.92(a)(4)

Device Description

The MyLab40 is a compact console ultrasound system used to perform general diagnostic ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Doppler, 3D/4D, Color Flow Mapping and on lower frequency probes, Tissue Enhancement Imaging (TEI). The system is equipped with a LCD color display and can drive Phased Array (PA), Convex Array (CA), Linear Array (LA) and Doppler probes.
The MyLab40 is able to produce Real Time 2D images and 3D images in manual mode with all probes. The system in combination with the BC431 or BS230 probe, offer the possibility to also produce automatic 3D and Real Time 4D images. The MyLab40 is manufactured under an ISO9001:2000 and ISO13485:2003 certified quality system.

807.92(a)(5)

Intended Use(s)

The MyLab40 is a compact console ultrasound system used to perform general diagnostic ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organ, Musculoskeletal (Conventional & Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic.

807.92(a)(6) **Technological Characteristics**

ESAOTE believes that the MyLab40 is substantially equivalent to the Esaote's MyLab20 product (K043588, K053154 and K061755) and the Esaote's MyLab30 product (K040596, K052805 and K060827).

	MyLab40 To be cleared via this submission	**MyLab30 K040596 K052805* K060827****	**MyLab20 K043588 K053154*** K061755****
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	NO
• Peripheral Vascular	YES	YES	YES
• Neonatal Cephalic	YES	YES	YES
• Adult Cephalic	YES	YES	NO
• Small organ	YES	YES	YES
• Musculoskeletal (conventional & superficial)	YES	YES	YES
• Abdominal	YES	YES	YES
• OB/Fetal	YES	YES	YES
• Transvaginal	YES	YES	YES
• Transrectal	YES	YES	YES
• Pediatric	YES	YES	YES
• Intraoperative: Abdominal	YES	YES*	YES****
• Other: Urological	YES	YES**	YES****
Probe Technology			
• Annular Array	NO	NO	NO
• Phased Array	YES	YES	NO
• Linear array	YES	YES	YES
• Convex Array	YES	YES	YES
Modes of operation	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI, 3D/4D	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI, 3D/4D**	2D, M-Mode, PW, CFM, Amplitude Doppler, TEI, 3D/4D***
Additional Modes of operation:			
• Compound Imaging	YES	YES**	No
• CMM	YES	YES**	No
• VPAN	YES	YES**	No
• CnTI	YES	YES**	No
• Strain Rate Quantification	YES	YES**	No

	MyLab40 **To be cleared via this *submission***	**MyLab30** **K040596** **K052805*** **K060827****	**MyLab20** **K043588** **K053154***** **K061755******
• TVM	YES	YES**	No
Imaging Frequencies	2.0 - 16 MHz	2.0 - 16 MHz	2.7 - 15 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,* 8.0 MHz	*2.7, 3.5, 5.0,* 6.3 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° ABS621: 25° 35° ABS424: 45° BS230KIT: 12.5° 20° ABS15: 45°	ABS421: 20° 30° ABS523: 45° ABS123: 3.8° ABS621: 25° 35° ABS424: 45° BS230KIT: 12.5° 20° ABS15: 45°	ABS421: 20° 30° ABS523: 45° ABS123: 3.8° ABS621: 25° 35° ABS424: 45° ABS15: 45°
Display Type	SVGA	SVGA	SVGA
Monitor	LCD	LCD	LCD CRT
Digital Archival Capabilities	YES	YES	YES
DICOM Classes:			
• Image Storage	YES	YES	NO
• Multiframe Image Storage	YES	YES	NO
• Basic Grayscale Print Management	YES	YES	NO
• Basic Color Print *Management*	YES	YES	NO
• Secondary Capture Image Storage	YES	YES	NO
• Modality Worklist	YES	YES	NO
• Storage Commitment Push Model	YES	YES	NO
• Modality Performed *Procedure Step*	YES	YES	NO
VCR / Page Printer	YES	YES	YES
M&A Capabilities	Cardiac, Vascular, OB, GYN and general purpose measurements	Cardiac, Vascular, OB, GYN and general purpose measurements	Cardiac, Vascular, OB, GYN and general purpose measurements

	MyLab40 **To be cleared via this *submission***	**MyLab30** **K040596** **K052805*** **K060827****	**MyLab20** **K043588** **K053154***** **K061755******
Weight	60 kg (excl. monitor)	10 kg	60 kg (excl. monitor)
Dimensions	*135 (H) x 54 (W) x 80* (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	*135 (H) x 54 (W) x 80* (D) cm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2007

Esaote Europe B.V.
% Ms. Carrie Graham
Consultant
The Anson Group
11460 N. Meridian St., Ste. 150
CARMEL IN 46032

Re: K070903
Trade Name: MyLab40
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: May 21, 2007
Received: May 22, 2007

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 MyLab40, as described in your premarket notification:

Transducer Model Number

BC431	LA532E	LA424
BS230	LA435	TEE022
PA230E	CA421	TEE122
PA121E	CA621	IOE323
PA122E	CA631	EC123
PA023E	CA123	2.0 CW Probe
LA523	CA431	5.0 CW Probe
LA522E	CA430E	

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 (240) 276-3150 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 Ewa Czerska at (240) 276-3666.

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)

Indications for Use

510(k) Number (if known): K070903

Device Name: MyLab40

Indications For Use:

Esaote's MyLab40 is a compact console ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal and Other: Urologic.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070903

Diagnostic Ultrasound Indications for Use Form

Model 2750 (MyLab40)

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N[2]	N[3,4,9]
Abdominal		N	N	N	N	N	N		N[2]	N[3,4,5,7,9]
Intraoperative Abdominal		N	N	N		N	N		N[2]	N[3,5,7]
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N[2]	N[3,5,9]
Small Organ (specify) [1]		N	N	N	N	N	N		N[2]	N[3,5,7,9]
Neonatal Cephalic		N	N	N	N	N	N		N[2]	N[3]
Adult Cephalic		N	N	N	N	N	N		N[2]	N[3]
Cardiac		N	N	N	N	N			N[2]	N[3,4,6,8,9]
Transesophageal		N	N	N	N	N	N		N[2]	N[3,4,6,8]
Transrectal		N	N	N		N	N		N[2]	N[3,7,9]
Transvaginal		N	N	N		N	N		N[2]	N[3,7,9]
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N[2]	N[3,5,9]
Laparoscopic										
Musculo-skeletal Conventional		N	N	N	N	N	N		N[2]	N[3,5,9]
Musculo-skeletal Superficial		N	N	N	N	N	N		N[2]	N[3,5,9]
Other (Urological)		N	N	N	N	N	N		N[2]	N[3,5,7,9]

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)
Compound Imaging
[4] Compass M-Mode (CMM)
[5] VPAN
[6] Tissue Velocity Mapping (TVM)
[7] CnTI
[8] XStrain
[9] 3D/4D Imaging

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Prescription Use (Per 21 CFR 801.109)

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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(1)	N(2,3,4,9]
Abdominal		N	N	N		N	N		N(1)	N(2,3,4,5,9]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N(1)	N(2,3,5,9]
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N(1)	N(2,3,5,9)
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)		N	N	N		N	N		N(1)	N(2,3,5,7,9)

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

[1] Applicable combined modes: B+M+PW+CW+CFM+PD
[2] Tissue Enhancement Imaging (TEI)
[3] Compound Imaging
[4] Compass M-Mode (CMM)
[5] VPAN
[6] Tissue Velocity Mapping (TVM)
[7] CnTI
[8] XStrain
[9] 3D/4D Imaging

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Division of Reproductive, Abdominal,
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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[1]	N[2,3,5,7,9]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N[1]	N[2,3]
Cardiac		N	N	N	N	N	N		N[1]	N[2,3,4,6,8,9]
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

[1] Applicable combined modes: B+M+PW+CW+CFM+PD
[2] Tissue Enhancement Imaging (TEI)
[3] Compound Imaging
[4] Compass M-Mode (CMM)
[5] VPAN
[6] Tissue Velocity Mapping (TVM)
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[8] XStrain
[9] 3D/4D Imaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
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PA230E

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(1)	N[2,3,4,5,7]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N(1)	N[2,3]
Cardiac		N	N	N	N	N	N		N(1)	N[2,3,4,6,8]
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

[1] Applicable combined modes: B+M+PW+CW+CFM+PD
[2] Tissue Enhancement Imaging (TEI)
[3] Compound Imaging
[4] Compass M-Mode (CMM)
[5] VPAN
[6] Tissue Velocity Mapping (TVM)
[7] CnTI
[8] XStrain
[9] 3D/4D Imaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
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PA121E

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(1)	N[2,3,4,5,7]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N(1)	N[2,3,4,6,8]
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N(1)	N[2,3,5]
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

[1] Applicable combined modes: B+M+PW+CW+CFM+PD
[2] Tissue Enhancement Imaging (TEI)
[3] Compound Imaging
[4] Compass M-Mode (CMM)
[5] VPAN
[6] Tissue Velocity Mapping (TVM)
[7] CnTI
[8] XStrain
[9] 3D/4D Imaging

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Division of Reproductive, Abdominal,
and Radiological Devices
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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 Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N[1]	N(2,3,5)
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N[1]	N(2,3)
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N[1]	N(2,3,4,6,8)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N[1]	N(2,3,5)
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

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[2] Tissue Enhancement Imaging (TEI)
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[6] Tissue Velocity Mapping (TVM)
[7] CnTI
[8] XStrain
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070903

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 Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N(1)	N(2,3,5)
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N(1)	N(2,3)
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N(1)	N(2,3,4,6,8)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N(1)	N(2,3,5)
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

[1] Applicable combined modes: B+M+PW+CW+CFM+PD
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070903

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(2)	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic		N	N	N		N	N		N(2)	N(3,4)
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N(2)	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)										

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

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)
[4] Compound Imaging
[5] Compass M-Mode (CMM)
[6] VPAN
[7] Tissue Velocity Mapping (TVM)
[8] CnTI
[9] XStrain
[10] 3D/4D Imaging

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LA522E

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[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)										

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

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)
[4] Compound Imaging
[5] Compass M-Mode (CMM)
[6] VPAN
[7] Tissue Velocity Mapping (TVM)
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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[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)										

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

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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(2)	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N(2)	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)										

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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[2]	N[3,4,5]
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)		N	N	N		N	N		N[2]	N[3,4,6,8]

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	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[2]	N[3,4,5]
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)		N	N	N		N	N		N[2]	N[3,4,6,8]

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Ophthalmic										
Fetal		N	N	N		N	N		N[2]	N[3,4,5]
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)		N	N	N		N	N		N[2]	N[3,4,6,8]

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	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[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic		N	N	N		N	N		N[2]	N[3,4]
Adult Cephalic										
Cardiac		N	N	N		N	N		N[2]	N[3,4,5,7,9]
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)										

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	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[2]	N[3,4,5]
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)		N	N	N		N	N		N[2]	N[3,4,6,8]

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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[2]	N[3,4,5]
Abdominal		N	N	N		N	N		N[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)		N	N	N		N	N		N(2)	N[3,4,6,8]

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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[2]	N[3,4,5,6,8]
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N[2]	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N[2]	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N[2]	N[3,4,6]
Other (Urological)										

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[8] CnTI
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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 Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N[1]	N[2,3,4,6,8]
Transesophageal		N	N	N	N	N	N		N[1]	N[2,3,4,6,8]
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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TEE122

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 Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N(1)	N[2,3,5]
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N(1)	N[2,3,4,6,8]
Transesophageal		N	N	N	N	N	N		N(1)	N[2,3,4,6,8]
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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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(2)	N[3,4,5,6,8]
Intraoperative Abdominal		N	N	N		N	N		N(2)	N[3,4,6,8]
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N(2)	N[3,4,6]
Small Organ (specify) [1]		N	N	N		N	N		N(2)	N[3,4,6,8]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N(2)	N[3,4,6]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N(2)	N[3,4,6]
Muscolo-skeletal Superficial		N	N	N		N	N		N(2)	N[3,4,6]
Other (Urological)										

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[7] Tissue Velocity Mapping (TVM)
[8] CnTI
[9] XStrain
[10] 3D/4D Imaging

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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[1]	N[2,3,4]
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		N[1]	N[2,3,7]
Transvaginal		N	N	N		N	N		N[1]	N[2,3,7]
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)		N	N	N		N	N		N[1]	N[2,3,5,7]

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

[1] Applicable combined modes: B+M+PW+CW+CFM+PD
[2] Tissue Enhancement Imaging (TEI)
[3] Compound Imaging
[4] Compass M-Mode (CMM)
[5] VPAN
[6] Tissue Velocity Mapping (TVM)
[7] CnTI
[8] XStrain
[9] 3D/4D Imaging

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2.0 CW Probe

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 Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
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

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)
[4] Compound Imaging
[5] Compass M-Mode (CMM)
[6] VPAN
[7] Tissue Velocity Mapping (TVM)
[8] CnTI
[9] XStrain
[10] 3D/4D Imaging

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5.0 CW Probe

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 Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
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

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)
[4] Compound Imaging
[5] Compass M-Mode (CMM)
[6] VPAN
[7] Tissue Velocity Mapping (TVM)
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The following section is page numbered independently from the remainder of the submission.

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Indications for Use for Transducers / Biopsy Attachments

Probe	Type	Indications for Use	Clearance Method
PA230E	Phased Array	Abdominal, Adult Cephalic, Cardiac	Cleared via K040596
PA121E	Phased Array	Abdominal, Cardiac, Peripheral Vascular	Cleared via K050326 & Memorandum to File referencing K040596
PA122E	Phased Array	Pediatric, Neonatal Cephalic, Cardiac, Peripheral Vascular	Cleared via K040596
PA023E	Phased Array	Pediatric, Neonatal Cephalic, Cardiac, Peripheral Vascular	Cleared via K050326 & Memorandum to File referencing K040596
LA523	Linear Array	Abdominal, Neonatal Cephalic, Small organ, Peripheral Vascular, Pediatric, Musculoskeletal Conventional & Superficial	Cleared via K043588 & 040596
LA522E	Linear Array	Abdominal, Small organ, Peripheral Vascular, Pediatric, Musculoskeletal Conventional & Superficial	Cleared via K050326 & Memorandum to File referencing K040596
LA435	Linear Array	Abdominal, Small organ, Peripheral Vascular, Pediatric, Musculoskeletal Conventional & Superficial	Cleared via Memorandum to File referencing K040596
CA421	Convex Array	Fetal, Abdominal, Pediatric, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological	Cleared via K040596

Indications for Use for Transducers / Biopsy Attachments

Probe	Type	Indications for Use	Clearance Method
CA621	Convex Array	Fetal, Abdominal, Pediatric, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological	Cleared via K050326 & Memorandum to File referencing K040596
CA123	Convex Array	Abdominal, Small organ, Cardiac, Pediatric, Peripheral Vascular, Neonatal Cephalic, Musculoskeletal Conventional & Superficial	Cleared via K050326 & Memorandum to File referencing K040596
CA431	Convex Array	Fetal, Abdominal, Pediatric, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological	Cleared via Memorandum to File referencing K050326
CA631	Convex Array	Fetal, Abdominal, Pediatric, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological	Cleared via Memorandum to File referencing K050326

Indications for Use for Transducers / Biopsy Attachments

Probe	Type	Indications for Use	Clearance Method
LA532E	Linear Array	Abdominal, Small organ, Pediatric, Peripheral Vascular, Musculoskeletal Conventional & Superficial	Cleared via K050326 & Memorandum to File referencing K040596
CA430E	Convex Array	Fetal, Abdominal, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological	Cleared via K050326 & Memorandum to File referencing K040596
LA424	Linear Array	Abdominal, Small organ, Pediatric, Peripheral Vascular, Musculoskeletal Conventional & Superficial	Cleared via K050326 and Memorandum to File referencing K040596
TEE022	Linear Array	Cardiac, Transesophageal	Cleared via K040596
TEE122	Linear Array	Pediatric Cardiac, Transesophageal	Via this submission Cleared via Memorandum to File referencing K040596
IOE323	Convex Array	Abdominal Intraoperative Abdominal, Small organ, Pediatric, Peripheral Vascular, Musculoskeletal Conventional & Superficial	Cleared via K052805 & K061755

Indications for Use for Transducers / Biopsy Attachments

Probe	Type	Indications for Use	Clearance Method
EC123	Linear Array	Fetal, Urological, Transrectal, Transvaginal	Cleared via K040596
BS230	Phased Array	Abdominal, Adult Cephalic, Cardiac	Cleared via K060827
BC431	Convex Array	Fetal, Abdominal, Pediatric, Peripheral Vascular, Urological	Cleared via K060827
2.0 CW	Doppler Array	Cardiac, Peripheral Vascular	Cleared via K052805 Via this submission
5.0 CW	Doppler Array	Cardiac, Peripheral Vascular	Via this submission Cleared via K052805

Indications for Use for Transducers / Biopsy Attachments

Biopsy Attachments	Type	Indications for Use	Clearance Method
ABS421	Biopsy attachment	CA421, CA430E & CA431- Fetal, Abdominal, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological	Cleared via K053154 and via this submission
ABS621	Biopsy attachment	CA621 & CA631 - Fetal, Abdominal, Pediatric, Small organ, Peripheral Vascular, Musculoskeletal Conventional & Superficial, Urological	Cleared via K053154 and via this submission
ABS523	Biopsy attachment	LA523, LA522E & LA532E - Abdominal, Small organ, Peripheral Vascular, Pediatric, Musculoskeletal Conventional & Superficial	Cleared via K053154 and via this submission
ABS424	Biopsy attachment	LA424 & LA435- Abdominal, Small organ, Pediatric, Peripheral Vascular, Musculoskeletal Conventional & Superficial	Cleared via K053154 and via this submission
ABS123	Biopsy attachment	EC123 - Fetal, Urology, Transrectal, Transvaginal	Cleared via K040596

Indications for Use for Transducers / Biopsy Attachments

Biopsy Attachments	Type	Indications for Use	Clearance Method
BS230 Kit	Biopsy attachment	BS230 - Abdominal, Adult Cephalic, Cardiac	Cleared via K060827
ABS15	Biopsy attachment	IOE323 - Abdominal, Small organ, Pediatric, Peripheral Vascular, Musculoskeletal Conventional & Superficial	Cleared via K052805