K041552

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Special 510(k) Premarket Notification GE Healthcare - GE Vivid 7 and EchoPAC BT04 June 8, 2004

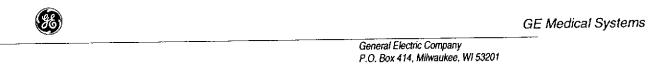
JUL 0 2 2004

Attachment B:

Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92(c).

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Section a):

1.	Submitter:	GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC PO Box 414, Milwaukee, WI 53201
	Contact Person:	Allen Schuh, Manager, Safety and Regulatory Engineering Telephone: 414-647-4385; Fax: 414-647-4090
	Date Prepared:	June 8, 2004
2.	<u>Device Name</u> :	GE Vivid 7 Diagnostic Ultrasound System with EchoPAC BT04 Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX
~	Marketed Devices	CE Vivid 7 Diagoostic Ultrasound System, K003931/K031663 (90-IYO/IYN/ITX

3. <u>Marketed Device</u>: GE Vivid 7 Diagnostic Ultrasound System K003931/K031663 (90-IYO/IYN/ITX) A device currently in commercial distribution.

4. <u>Device Description</u>: The GE Vivid 7 Diagnostic Ultrasound is a full featured echocardiography imaging and analysis system. It consists of a mobile console approximately 65 cm wide, 96 cm deep and 139 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and a color video CRT display. This modification will provide users with enhanced ability to evaluate wall motion during echocardiography.

5. <u>Indications for Use</u>: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal (including renal and GYN); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional; Urology (including prostate), Transesophageal; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

6. <u>Comparison with Predicate Device</u>: The GE Vivid 7 BT04 is of a comparable type and substantially equivalent to the current GE Vivid 7 with added features equivalent to the GE Voluson 730, GE LOGIQ 9 and Philips SONOS 7500. It has the same technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has the same intended uses and basic operating modes as the predicate devices.

Section b):

1. <u>Non-clinical Tests</u>: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. <u>Conclusion</u>: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Vivid 7 BT04 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



JUL 0 2 2004

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Allen Schuh Manager, GE Ultrasound Safety and Regulatory Engineering GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 4855 West Electric Avenue WEST MILWAUKEE WI 53219

Re: K041552

Trade Name: GE Vivid 7 Ultrasound System 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: June 8, 2004 Received: June 9, 2004

Dear Mr. Schuh:

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 GE Vivid 7 Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>3.5C</u>	<u>3S</u>	<u>8T</u>
<u>3.5C</u> <u>5C</u> <u>8C</u>	<u>5S</u>	<u>9T</u>
<u>8C</u>	<u>7S</u>	<u>P2D</u> <u>P6D</u>
<u>M7C</u>	<u>10S</u>	<u>P6D</u>
<u>7L</u>	<u>M3S</u>	<u>i8L</u>
<u>10L</u>	<u>E8C</u>	<u>i13L</u> 3V
<u>12L</u>	<u>6T</u>	<u>3V</u>
<u>M12L</u>	<u>7T</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.

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Page 2 - Mr. Schuh

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

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

Sincerely yours,

Manay C Brogdon

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

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 Ultrasound System

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

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р	Р	P	Р	P	Р	Р	P	N
Abdominal ^[1]	Р	Р	Р	Р	Р	Р	Р	Р	Р	P	N
Pediatric	Р	P	Р	P	Р	Р	Р	Р	Р	Р	N
Small Organ ^[2]	Р	Р	Р		P	Р	Р	Р	N	P	
Neonatal Cephalic	Р	Р	P	Р	Р	Р	Р	Р	Р	Р	
Adult Cephalic	Р	P	Р	P	Р	Р	P	P	Р	N	N
Cardiac ^[3]	Р	Р	Р	Р	P	P	Р	Р	Р	<u>N</u>	N
Peripheral Vascular	Р	Р	Р	Р	Р	Р	Р	Р	N	Р	
Musculo-skeletal Conventional	Р	Р	Р		Р	Р	<u>Р</u>	Р	N	Р	
Musculo-skeletal Superficial											
Other ^[4]	Р	Р	Р	Р	Р	Р	Р	Р	P	P	N
Exam Type, Means of Access											
Transesophageal	Р	Р	р	P	Р	P	Р	P	Р	<u>N</u>	
Transrectal	Р	Р	Р		P	Р	Р	Р		N	
Transvaginal	Р	Р	Р		Р	P	P	Р		N	
Transuretheral											
Intraoperative ^[5]	Р	Р	Р		Р	Р	Р	Р		N	
Intraoperative Neurological											
Intravascular									<u> </u>		
Laparoscopic											

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

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

[*] RT3D is Realtime 3D / 4D volume tissue scan acquisition;

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 3.5C Transducer

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

		Mode of Operation										
Clinical Application Anatomy/Region of Interest	8	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other	
Ophthalmic												
Fetal / Obstetrics	Р	P	Р		Р	Р	Р	Р	Р	P		
Abdominal ^[1]	Р	Р	Р		Р	Р	Р	<u>Р</u>	Р	P		
Pediatric	Р	Р	Р		Р	P	Р	Р	Р	P		
Small Organ (specify)											[
Neonatal Cephalic												
Adult Cephalic											 	
Cardiac												
Peripheral Vascular	N	N	N		N	N	N	N	N	N		
Musculo-skeletal Conventional			1			ļ		_				
Musculo-skeletal Superficial					ļ							
Other ^[4]	P	Р	Р		P	<u>Р</u>	<u>Р</u>	Р	Р	Р	ļ	
Exam Type, Means of Access							ļ					
Transesophageal			<u> </u>					<u> </u>				
Transrectal												
Transvaginal												
Transuretheral			<u> </u>					ļ	ļ		ļ	
Intraoperative (specify)								ļ				
Intraoperative Neurological				ļ		ļ	 				[
Intravascular				ļ					ļ		<u> </u>	
Laparoscopic				<u> </u>		<u> </u>	L	<u> </u>				

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

Notes: [1] Abdominal includes GYN;

[4] Other use includes Urology;

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 5C Transducer

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

		Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other	
Ophthalmic												
Fetal / Obstetrics	Р	P	Р		Р	Р	P	Р		Р		
Abdominal ^[1]	Р	Р	Р		Р	P	Р	Р		Р		
Pediatric	Р	Р	P		Р	Р	Р	P		P		
Small Organ (specify)												
Neonatal Cephalic								:				
Adult Cephalic												
Cardiac												
Peripheral Vascular	Р	Р	P		Р	Р	Р	P		Р		
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other ^[4]	N	N	N		N	N	N	N		N		
Exam Type, Means of Access												
Transesophageal												
Transrectal												
Transvaginal												
Transuretheral												
Intraoperative (specify)												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

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

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[4] Other use includes Urology;

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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(Division Sign-Off) / () Division of Reproductive, Abdominal, and Radiological Devices, KD14552 510(k) Number _______

Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 8C Transducer

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

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	Р	P	Р		Р	P	Р	Р		Р	
Pediatric	P	Р	Р		Р	Р	Р	Р		Р	
Small Organ (specify)	Р	Р	Р		Р	Р	Р	Р		P	
Neonatal Cephalic	Ρ	P	Р	[Р	Р	Р	Р		Р	
Adult Cephalic				1							
Cardiac											
Peripheral Vascular	Р	P	Р		Р	Р	Р	Р		Р	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial								ļ			
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal	<u> </u>										
Transuretheral								<u> </u>			
Intraoperative (specify)				<u> </u>							
Intraoperative Neurological				ļ			<u> </u>				
Intravascular				<u> </u>							
Laparoscopic											

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

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with M7C Transducer

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

		Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other	
Ophthalmic												
Fetal / Obstetrics	P	Р	Р		Р	Р	Р	Р	N	P		
Abdominal ^[1]	Р	Р	Р		Р	Р	Р	Р	N	Р		
Pediatric	P	р	P		Р	Р	Р	Р	N	Р		
Small Organ (specify)	<u>P</u>	Р	<u>P</u>		Р	Р	Р	Р	N	Р		
Neonatal Cephalic												
Adult Cephalic												
Cardiac							.	L				
Peripheral Vascular	Р	Р	P		Р	P	Р	Р	N	ą		
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other ^[4]	N	N	N		N	N	N	N	N	N		
Exam Type, Means of Access												
Transesophageal												
Transrectal												
Transvaginal												
Transuretheral										·		
Intraoperative (specify)				[
Intraoperative Neurological												
Intravascular			ļ <u> </u>									
Laparoscopic											1	

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

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[4] Other use includes Urology;

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 7L Transducer

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

		Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics												
Abdominal									ļ			
Pediatric	Р	Р	Р		Р	Р	Р	Р	N	P		
Small Organ ^[2]	Р	P	P	ļ	P	P	P	P	N	<u>Р</u>		
Neonatal Cephalic												
Adult Cephalic				_	<u> </u>							
Cardiac			1		ļ			ļ				
Peripheral Vascular	Р	Р	Р		Р	<u>Р</u>	P	P	<u>N</u>	Р		
Musculo-skeletal Conventional	P	P	Р		P	P	Р	P	N	P		
Musculo-skeletal Superficial								ļ				
Other ¹⁴¹		_		ļ				<u> </u>			ļ	
Exam Type, Means of Access									Į			
Transesophageal		ļ		<u> </u>	ļ			 		<u></u>		
Transrectal				 		i			ļ			
Transvaginal			ļ	ļ	ļ	ļ	ļ		ļ	 		
Transuretheral			<u> </u>			<u> </u>		<u> </u>		ļ		
Intraoperative (specify)			ļ	<u> </u>	_	1	ļ		.l		ļ	
Intraoperative Neurological										<u> </u>	ļ	
Intravascular		<u> </u>			ļ	ļ	ļ	<u> </u>				
Laparoscopic												

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

Notes: [2] Small organ includes breast, testes, thyroid.

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 10L Transducer

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

		Mode of Operation											
Clinical Application	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse			
Anatomy/Region of Interest													
Ophthalmic				 									
Fetal / Obstetrics			┨		<u> </u>	 				······			
Abdominal		·	<u> </u>	<u> </u>	<u> </u>								
Pediatric	P	P	P	 	P	P	P	P	N	Р			
Small Organ ^[2]	Р	Р	Р		Р	<u>Р</u>	P.	<u>Р</u>	N	Р			
Neonatal Cephalic				<u> </u>		ļ							
Adult Cephalic				ļ		ļ							
Cardiac				<u> </u>	ļ								
Peripheral Vascular	Ρ_	Р	P		Р	Р.	Р	Р	N	Р			
Musculo-skeletal Conventional	P	P	Р	r	Р	<u>р</u>	P	P	N	P			
Musculo-skeletal Superficial							ļ		 				
Other (specify)		 	<u> </u>			_		<u> </u>	ļ				
Exam Type, Means of Access			<u> </u>	<u> </u>	↓			·					
Transesophageal		ļ			ļ		1	. <u> </u>	Į				
Transrectal									ļ	ļ			
Transvaginal				ļ			<u> </u>	<u> </u>					
Transuretheral							ļ	<u> </u>					
Intraoperative ^[5]	Р	Р	P		P		Р	Р	<u>N</u>	<u>N</u>			
Intraoperative Neurological							<u> </u>	<u> </u>	<u> </u>	. <u> </u>			
Intravascular								ļ	<u> </u>		 		
Laparoscopic						<u> </u>	<u> </u>	ļ	<u> </u>	<u> </u>	<u> </u>		

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

Notes: [2] Small organ includes breast, testes, thyroid.

[5] Intraoperative includes abdominal, thoracic, and vascular.

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Division of Reproductive, Abdominal, and Badiological Devices K041552 510(k) Number

Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 12L Transducer

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

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics			<u> </u>								
Abdominal						·					
Pediatric	P	Р	P		<u>Р</u>	Р	<u>Р</u>	P	N	P	
Small Organ ^[2]	Р	P	Р	ļ	P	P	P	P	N	Р	
Neonatal Cephalic											
Adult Cephalic			<u>_</u>	ļ	<u> </u>						
Cardiac								<u> </u>			
Peripheral Vascular	<u> </u>	P	P _	ļ	P	P	P	P	<u>N</u>	P	
Musculo-skeletal Conventional	Р	Р	Р		<u>Р</u>	P	P	<u> </u>	<u>N</u>	Р	
Musculo-skeletal Superficial					ļ						
Other (specify)			ļ	ļ		ļ		ļ. <u> </u>			
Exam Type, Means of Access			ļ				-	_		 	
Transesophageal		<u> </u>		_	<u> </u>		<u> </u>				
Transrectal					<u> </u>	<u> </u>		<u> </u>			
Transvaginal		ļ					 				i
Transuretheral		ļ						<u> </u>		ļ	
Intraoperative (specify)					<u> </u>	_	 			 	 -
Intraoperative Neurological		ļ		<u> </u>							
Intravascular		ļ		.		1			<u> </u>	 	
Laparoscopic	1						1		1	l	

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

Notes: [2] Small organ includes breast, testes, thyroid.

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with M12L Transducer

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

······································		Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics												
Abdominal								 				
Pediatric	P	Р	<u>Р</u>		Р	P	Р	P	N	Р		
Small Organ ^[2]	Р	P	P		Р	<u>Р</u>	Р	Р	N	<u>P</u>	ļ	
Neonatal Cephalic		Į	<u> </u>						ļ		ļ	
Adult Cephalic			ļ									
Cardiac	-		 			ļ		ļ		ļ	ļ	
Peripheral Vascular	Р	Р	Р		P	<u>Р</u>	Р	Р	N	<u>Р</u>		
Musculo-skeletal Conventional	Р	P_	P		Р	P	Р	Р	<u>N</u>	P		
Musculo-skeletal Superficial				ļ	ļ	ļ		ļ				
Other (specify)						ļ		ļ	ļ		<u> </u>	
Exam Type, Means of Access		ļ				I		ļ	ļ			
Transesophageal				ļ	 	1						
Transrectal			1		<u> </u>	ļ		ļ			ļ	
Transvaginal				 	ļ	ļ		ļ	ļ	ļ		
Transuretheral						<u> </u>	ļ	ļ		ļ		
Intraoperative (specify)	Р	P_	Р.	<u> </u>	Р	P	Р	Р	<u>N</u>	P		
Intraoperative Neurological					<u> </u>	Į		ļ				
Intravascular		ļ		ļ	ļ	<u> </u>			 	ļ		
Laparoscopic				ļ		<u> </u>						

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

Notes: [2] Small organ includes breast, testes, thyroid.

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 3S Transducer

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

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P	Р	Р	Р	Р	Р	Р	N	
Abdominal ^[1]	P	P	Р	Р	Р	<u>Р</u>	Р	P	P	N	
Pediatric	Р	Ρ_	P	Р	Р	Р	Р	Р	Р	N	
Small Organ (specify)			<u> </u>								
Neonatal Cephalic					<u> </u>						
Adult Cephalic	Р	Р	Р	Р	Р	P	Р	P	Р	N	
Cardiac ^[3]	Р	P	Р	P	P	P	P	Р	Р	<u>N</u>	
Peripheral Vascular								<u> </u>			
Musculo-skeletal Conventional			ļ	L	·	[ļ
Musculo-skeletal Superficial			L					ļ	_		
Other ^[4]	Р	P	Р	Р	P	P	P	Р	Р	<u>N</u>	
Exam Type, Means of Access				<u> </u>		ļ					ļ
Transesophageal						ļ	<u> </u>	ļ	ļ		
Transrectal							<u> </u>	ļ	ļ		
Transvaginal								<u> </u>	<u> </u>		ļ
Transuretheral				ļ	<u> </u>	ļ	 	ļ		<u> </u>	<u> </u>
Intraoperative (specify)			1				<u> </u>	ļ	ļ		<u> </u>
Intraoperative Neurological											
Intravascular				ļ	<u> </u>			ļ	<u> </u>	 _	
Laparoscopic				<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	

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

Notes: [1] Abdominal includes GYN;

[3] Cardiac is Adult and Pediatric;

[4] Other use includes Urology;

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 5S Transducer

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

					Mode	of Op	eratior	1			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	Р	Р	P	Р	Р	Р	P	N	
Abdominal ^[1]	Р	Р	P	Р	P	Р	Р	Р	P	N	
Pediatric	Р	Р	Р	Р	P	Р	Р	P	Р	N	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic					<u> </u>			ļ			
Cardiac ^[3]	Р	Р	Р	P	Р.	<u>Р</u>	Р	<u>Р</u>	Р	N	
Peripheral Vascular				ļ		ļ					
Musculo-skeletal Conventional				ļ		<u> </u>		<u> </u>			
Musculo-skeletal Superficial						 		ļ			
Other ^[4]	Р	Р	Р	Р	Р	Р	P	Р	Р	N	
Exam Type, Means of Access						ļ	ļ				
Transesophageal											
Transrectal				ļ							
Transvaginal			 				ļ <u>-</u>		ļ		
Transuretheral						<u> </u>		 			ļ
Intraoperative (specify)				<u> </u>						ļ	
Intraoperative Neurological		ļ		ļ	ļ	ļ	ļ	ļ	ļ	 	
Intravascular					1	ļ	ļ	ļ	<u> </u>		
Laparoscopic						<u> </u>		J			

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

Notes: [1] Abdominal includes GYN;

[3] Cardiac is Adult and Pediatric;

[4] Other use includes Urology;

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 7S Transducer

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

					Mode	of Op	eratior	1			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic			ļ								
Fetal / Obstetrics	Р	P	<u>Р</u>	Р	Р	Р	Р	Р	P	N	
Abdominal ^[1]	Ρ	Р	P	Р	Р	Р	P	Р	Р	<u>N</u>	
Pediatric	Р	Р	Р	Р	Р	P	Р	P	Р	N	
Small Organ (specify)											
Neonatal Cephalic	_ P	Р	P	Р	P	Р	Р	<u>Р</u>	Р	<u>N</u>	
Adult Cephalic			ļ								
Cardiac ^[3]	P	Р	Р	Р	Р	P	Р	P	P	N	
Peripheral Vascular				L				ļ			
Musculo-skeletal Conventional			·		<u> </u>						
Musculo-skeletal Superficial											
Other (specify)				ļ	<u> </u>		ļ	ļ			
Exam Type, Means of Access							ļ	ļ			
Transesophageal							 				
Transrectal						ļ		ļ			
Transvaginal					_	 	ļ	ļ	ļ		
Transuretheral						ļ	ļ				
Intraoperative (specify)					<u> </u>				ļ		
Intraoperative Neurological							ļ				
Intravascular		L			_		<u> </u>	 		 	ļ
Laparoscopic							<u> </u>		<u> </u>		<u> </u>

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

Notes: [1] Abdominal includes GYN;

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology and GYN.

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 10S Transducer

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

	Mode of Operation Mode of Operation P W CW Color M Power Combined Harmonic Coded										
Clinical Application	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Anatomy/Region of Interest											
Ophthalmic			<u> </u>								
Fetal / Obstetrics											
Abdominal			ļ								
Pediatric	P	Р	P	Р	Р	<u>Р</u>	Р	Р	_P	N	
Small Organ (specify)											
Neonatal Cephalic	Р	Р	<u>P</u>	Р	P	Р	Р	Р	Р	N	
Adult Cephalic						 					
Cardiac ^[3]	Р	Р	Р_	Р	P	P	Р	Р	P	N	
Peripheral Vascular			 _	ļ		 					
Musculo-skeletal Conventional									 	 _	
Musculo-skeletal Superficial		İ	ļ				 		 _		
Other (specify)			ļ		ļ	 			ļ	ļ	
Exam Type, Means of Access						 			_		
Transesophageal			<u> </u>	ļ	ļ				 		
Transrectal				<u> </u>		ļ	ļ		 		
Transvaginal			<u> </u>				ļ	 	ļ		
Transuretheral											
Intraoperative (specify)						ļ. <u></u>		ļ		ļ	ļ
Intraoperative Neurological									ļ	ļ	ļ
Intravascular								<u> </u>			<u> </u>
Laparoscopic			1					<u> </u>	<u> </u>	<u> </u>	

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

Notes: [3] Cardiac is Adult and Pediatric.

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with M3S Transducer

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

					Mode	of Op	eratior	 ו			
Clinical Application Anatomy/Region of Interest	8	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P_	Р	P	Р	Р	P	P	N	
Abdominal ^[1]	P	Р	Р	Р	Р	<u>Р</u>	Р	P	P	<u>N</u>	
Pediatric	P	P	Р	P	Р	P	Р	Р	P	N	
Small Organ (specify)											
Neonatal Cephalic				ļ	ļ			ļ			
Adult Cephalic	P	Р	P	P	Р	<u>Р</u>	Р	P	P	<u>N</u>	
Cardiac ^[3]	_ Р	P	_P	Р	P	P	Р	<u>P</u>	Р	N	
Peripheral Vascular						ļ		ļ			
Musculo-skeletal Conventional			ļ		ļ						
Musculo-skeletal Superficial			ļ					<u> </u>			- <u></u>
Other (specify) ^[4]	Ρ	Р	Р	P	Р	<u>Р</u>	Р	P	P	N	
Exam Type, Means of Access				ļ	ļ	<u> </u>					
Transesophageal			ļ	ļ					ļ		
Transrectal		ļ									
Transvaginal		<u> </u>		ļ		<u> </u>		ļ		 	
Transuretheral			ļ	ļ				 	<u> </u>	 	
Intraoperative (specify)		l	ļ								
Intraoperative Neurological		ļ	-	ļ		Į	<u> </u>				
Intravascular		. <u></u>	ļ	ļ	 				ļ		
Laparoscopic		Į		<u>i</u>		<u> </u>		1		l	<u> </u>

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

Notes: [1] Abdominal includes Renal and GYN;

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology;

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with E8C Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	P	Р		P	P	Р	Р		N	
Abdominal ^[1]	Р	Р	P		Р	_P	Р	Р		N	
Pediatric											
Small Organ (specify)			<u> </u>								
Neonatal Cephalic											
Adult Cephalic											
Cardiac								i			
Peripheral Vascular								 			ļ
Musculo-skeletal Conventional							<u> </u>				
Musculo-skeletal Superficial											
Other ^[4]	P	Р	Р		Р	Р	P	Р		N	
Exam Type, Means of Access				ļ							
Transesophageal		l									
Transrectal	Ρ	Р	Р		Р	P	Р	Р		N	ļ
Transvaginal	Р	Р	Р		Р	Р	Р	Р		N	
Transuretheral											
Intraoperative (specify)								<u> </u>			
Intraoperative Neurological											
Intravascular					 _						
Laparoscopic										<u> </u>	

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

Notes: [1] Abdominal includes GYN/Pelvic;

[4] Other use includes Urology/Prostate;

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Division of Reproductive, Abdominal, and Radiological Devices, 510(k) Number _____K04(552)

Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 6T Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics			<u> </u>								
Abdominal			<u> </u>								
Pediatric											
Small Organ (specify)						ļ					
Neonatal Cephalic			ļ	 							
Adult Cephalic					ļ						
Cardiac	P	P	Р	P	<u>Р</u>	P	Р	P	Р	<u>N</u>	
Peripheral Vascular				ļ	 	ļ		ļ			
Musculo-skeletal Conventional					ļ						
Musculo-skeletal Superficial	·				ļ				 		
Other (specify)			ļ		 	ļ					
Exam Type, Means of Access						 	<u>-</u>		[_	
Transesophageal	Р	Р	Р	Р	P	Р	Р	P	P	<u>N</u>	
Transrectal		<u> </u>		l			 		ļ	 	-
Transvaginal				ļ		1			ļ		
Transuretheral			<u> </u>	<u> </u>			ļ	<u> </u>	1	ļ	
Intraoperative (specify)		<u> </u>	<u> </u>		1	<u> </u>					
Intraoperative Neurological		ļ		_					<u> </u>		
Intravascular		ļ		ļ		<u> </u>	ļ		ļ		┨────
Laparoscopic				<u> </u>	<u> </u>		<u> </u>		<u> </u>		ļ

N = new indication; P = previously cleared by FDA; E = added under Appendix E. Notes: [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 7T Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics					ļ						
Abdominal							•				
Pediatric			ļ		[
Small Organ (specify)											
Neonatal Cephalic				<u> </u>							
Adult Cephalic											
Cardiac	Р	Р	P	Р	Р	Р	Р	Р	Р	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access			1		ļ						
Transesophageal	Р	Р	<u>Р</u>	Р	Р	Р	Р	Р	Р	N	
Transrectal				 							
Transvaginal				ļ	<u> </u>						
Transuretheral											
Intraoperative (specify)			<u> </u>			<u> </u>		<u> </u>			
Intraoperative Neurological							ļ	ļ			
Intravascular								ļ			ļ
Laparoscopic						ļ					<u> </u>

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

Notes: [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 8T Transducer

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

	Mode of Operation PW CW Color Color M Power Combined Harmonic Coded										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic			· · · · · · · · · · · · · · · · · · ·								
Fetal / Obstetrics											
Abdominal		·									
Pediatric											
Small Organ (specify)											
Neonatal Cephalic				-							
Adult Cephalic				ļ	ļ	ļ					
Cardiac ^[3]	Р	P	Р	P	Р	Р	Р	Р	Р	N	
Peripheral Vascular					<u> </u>			ļ			
Musculo-skeletal Conventional			1			ļ		<u> </u>			
Musculo-skeletal Superficial						ļ					
Other (specify)						ļ		ļ			
Exam Type, Means of Access						ļ					
Transesophageal	Р	Р	P	P .	Р	P	P	Р	P	N	
Transrectal						ļ]			
Transvaginal				ļ		ļ	ļ				
Transuretheral				Į	ļ <u>.</u>	 		ļ			
Intraoperative (specify)				ļ		L	 		ļ		
Intraoperative Neurological									 		
Intravascular			ļ	ļ			ļ	- <u></u>			
Laparoscopic			<u> </u>	<u> </u>			<u> </u>		<u> </u>		

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

Notes: [3] Cardiac is Adult and Pediatric;

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 9T Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	в	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics			ļ								
Abdominal											
Pediatric											
Small Organ (specify)						 					
Neonatal Cephalic			1		 						
Adult Cephalic						ļ					
Cardiac ^[3]	Р	Р	P	P	Р	<u>Р</u>	P	P	P	N.	
Peripheral Vascular					ļ]			
Musculo-skeletal Conventional			<u> </u>	ļ	ļ		 				
Musculo-skeletal Superficial			1		ļ	 					
Other (specify)					ļ		ļ				
Exam Type, Means of Access											
Transesophageal	Р	P	Р	<u>Р</u>	P	P	P	P	Р	N	
Transrectal					ļ	<u> </u>					
Transvaginal				ļ	ļ		ļ	 	ļ		ļ
Transuretheral				ļ							
Intraoperative (specify)				1				ļ	ļ		
Intraoperative Neurological				ļ	<u> </u>			<u> </u>			
Intravascular	. <u> </u>	I		ļ	ļ	ļ			ļ		ļ
Laparoscopic]	<u> </u>			1	<u> </u>			

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

Notes: [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

[3] Cardiac is Adult & Pediatric

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with P2D Transducer

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

	Mode of Operation Power Control Coded										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler						Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics			1								
Abdominal			ļ								
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]			Р	Р							
Peripheral Vascular			Р	P		Ĺ					
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)			<u> </u>								
Exam Type, Means of Access			ļ								
Transesophageal			ļ								
Transrectal		[ļ	ļ							<u> </u>
Transvaginal											
Transuretheral						ļ			i		
Intraoperative (specify)						ļ		ļ			
Intraoperative Neurological						<u> </u>					
Intravascular			ļ	ļ							
Laparoscopic								1			<u> </u>

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

Notes: [3] Cardiac is Adult and Pediatric.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with P6D Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics				l							
Abdominal				<u> </u>							
Pediatric								-			
Small Organ (specify)											
Neonatal Cephalic					l						
Adult Cephalic											
Cardiac ^[3]			Р	P							
Peripheral Vascular			Р	P		 	<u> </u>				ļ
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal		ļ	_			<u> </u>	ļ				<u> </u>
Transrectal				ļ			l				
Transvaginal								ļ			_
Transuretheral						ļ	ļ				
Intraoperative (specify)									l		
Intraoperative Neurological											ļ
Intravascular				 	<u> </u>	1			<u></u>		
Laparoscopic						<u> </u>					<u> </u>

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

Notes: [3] Cardiac is Adult and Pediatric.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with i8L Transducer

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

					Mode	of Op	eratior	ı			
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	_ P	Р	P		P	Р	P	Р		<u>N_</u>	
Pediatric											
Small Organ (specify)					ļ						
Neonatal Cephalic						 					
Adult Cephalic		ļ					<u> </u>	 			
Cardiac ^[3]	Р	Р	Р		P	P	<u>Р</u>	Р		<u>N</u>	
Peripheral Vascular											
Musculo-skeletal Conventional					<u> </u>						
Musculo-skeletal Superficial						ļ	ļ				
Other (specify)			<u> </u>						. <u> </u>		
Exam Type, Means of Access				 							
Transesophageal			_				ļ		ļ		
Transrectal							ļ				
Transvaginal					_						
Transuretheral			<u> </u>	ļ			 				
Intraoperative ^[5]	Р	Р	Р	ļ	Р	P	P	Р		N	
Intraoperative Neurological					<u> </u>			ļ			
Intravascular				ļ	ļ	<u> </u>		ļ	1		
Laparoscopic								<u> </u>	<u> </u>		

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

Notes: [1] Abdominal is via Intraoperative;

[3] Cardiac is Adult and Pediatric via Intraoperative;

[5] Intraoperative includes abdominal, thoracic, and vascular.

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with i13L Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	B	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	<u>Р</u>		Р	Р	Р	Р		N	
Pediatric			· · ·								
Small Organ (specify)											
Neonatal Cephalic								ļ			
Adult Cephalic			1					ļ			
Cardiac ^[3]	P	Р	Р		Р	Р	Р	Р		N	
Peripheral Vascular											
Musculo-skeletal Conventional		l	<u> </u>								
Musculo-skeletal Superficial		<u> </u>	<u> </u>								
Other (specify)					ļ			 			
Exam Type, Means of Access											
Transesophageal					<u> </u>		ļ				
Transrectal							-	ļ			
Transvaginal											
Transuretheral					<u> </u>						
Intraoperative ⁽⁵⁾	Р	Р	P		P	Р	<u>Р</u>	P		N	
Intraoperative Neurological						ļ	 	ļ	 		
Intravascular						ļ		<u> </u>			
Laparoscopic								1	<u> </u>		

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

Notes: [1] Abdominal is via Intraoperative;

[3] Cardiac is Adult and Pediatric via Intraoperative;

[5] Intraoperative includes abdominal, thoracic, and vascular.

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid 7 with 3V Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	RT3D Mode*
Ophthalmic			_								
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N	N	<u>N</u>
Abdominal	N	N	N	N	N	N	<u>N</u>	N	N	N	N
Pediatric	N	N	N	N	N	N	N	N	N	N	N
Small Organ (specify)											1
Neonatal Cephalic			_ _			 		ļ			ļ
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	N
Cardiac	N	N	N	N	N	N	N	N	N	N	N
Peripheral Vascular			_		ļ		ļ				ļ
Musculo-skeletal Conventional				<u> </u>							
Musculo-skeletal Superficial			1			ļ		ļ	ļ		ļ
Other (specify) ^[4]	N	N	N	N	N	N	N	N	N	N	N
Exam Type, Means of Access							ļ				_
Transesophageal						<u> </u>		<u> </u>			
Transrectal			1						ļ		ļ
Transvaginal					ļ			ļ			
Transuretheral							ļ	ļ	 		
Intraoperative											
Intraoperative Neurological					ļ	ļ	ļ	ļ	ļ		
Intravascular			_	<u> </u>			ļ	ļ	L	ļ	<u> </u>
Laparoscopic					<u> </u>				<u> </u>		

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

Notes: [*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] RT3D is Realtime 3D / 4D volume tissue scan acquisition;

[3] Cardiac is Adult and Pediatric

[4] Other use includes Urology;

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