

JUL 02 2004

## Attachment B:

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



GE Medical Systems

General Electric Company  
 P.O. Box 414, Milwaukee, WI 53201

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

4. Device Description: 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. Indications for Use: 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. Comparison with Predicate Device: 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. Non-clinical Tests: 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. Conclusion: 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 02 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>5C</u>	<u>5S</u>	<u>9T</u>
<u>8C</u>	<u>7S</u>	<u>P2D</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>
<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 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 (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,



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

Enclosure(s)

**Diagnostic Ultrasound Indications for Use Form**  
**GE Vivid 7 Ultrasound System**

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

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

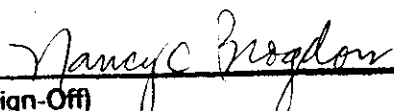
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[\*] 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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 1041552

Prescription User (Per 21 CFR 801.109)

**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:

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

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription User (Per 21 CFR 801.109)

**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:

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

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

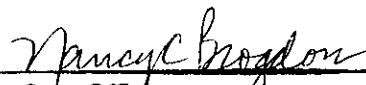
Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 and Radiological Devices  
 510(k) Number       K041552      

Prescription User (Per 21 CFR 801.109)

**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:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P		P	
Pediatric	P	P	P		P	P	P	P		P	
Small Organ (specify)	P	P	P		P	P	P	P		P	
Neonatal Cephalic	P	P	P		P	P	P	P		P	
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P		P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
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;

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Nancy Brogan*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 15041552

Prescription User (Per 21 CFR 801.109)



**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:

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

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

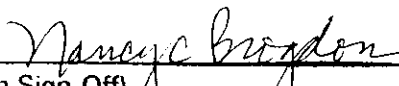
Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[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 of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041552

Prescription User (Per 21 CFR 801.109)

**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:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P	N	P	
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	N	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	N	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	N	P	
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
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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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number         K041552

**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:

Clinical Application	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
<i>Anatomy/Region of Interest</i>										
Ophthalmic										
Fetal / Obstetrics										
Abdominal										
Pediatric	P	P	P		P	P	P	P	N	P
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	N	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Peripheral Vascular	P	P	P		P	P	P	P	N	P
Musculo-skeletal Conventional	P	P	P		P	P	P	P	N	P
Musculo-skeletal Superficial										
Other (specify)										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative <sup>[5]</sup>	P	P	P		P		P	P	N	N
Intraoperative Neurological										
Intravascular										
Laparoscopic										

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

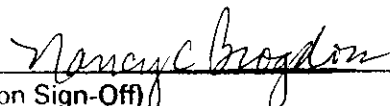
Notes: [2] Small organ includes breast, testes, thyroid.

[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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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

**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:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P	N	P	
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	N	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	N	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	N	P	
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

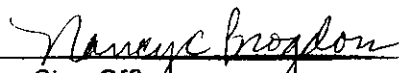
N = new indication; P = previously cleared by FDA; E = added under Appendix E

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number     K041552

**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:

Clinical Application Anatomy/Region of Interest	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
Ophthalmic										
Fetal / Obstetrics										
Abdominal										
Pediatric	P	P	P		P	P	P	P	N	P
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	N	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Peripheral Vascular	P	P	P		P	P	P	P	N	P
Musculo-skeletal Conventional	P	P	P		P	P	P	P	N	P
Musculo-skeletal Superficial										
Other (specify)										
Exam Type, Means of Access										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative (specify)	P	P	P		P	P	P	P	N	P
Intraoperative Neurological										
Intravascular										
Laparoscopic										

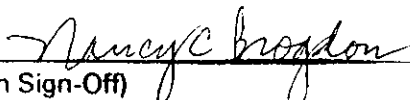
N = new indication; P = previously cleared by FDA; E = added under Appendix E

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041552

**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:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	N	
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	N	
Pediatric	P	P	P	P	P	P	P	P	P	N	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	N	
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	N	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal includes GYN;

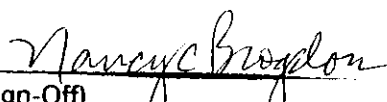
[3] Cardiac is Adult and Pediatric;

[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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041552

**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:

Clinical Application Anatomy/Region of Interest	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
Ophthalmic										
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	N
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	N
Pediatric	P	P	P	P	P	P	P	P	P	N
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	N
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	N
Exam Type, Means of Access										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative (specify)										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

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

Notes: [1] Abdominal includes GYN;

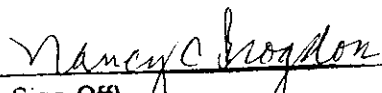
[3] Cardiac is Adult and Pediatric;

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

**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:

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

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

Notes: [1] Abdominal includes GYN;

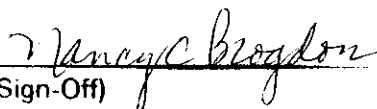
[3] Cardiac is Adult and Pediatric.

[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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 and Radiological Devices  
 510(k) Number K041552



**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:

Clinical Application	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
<i>Anatomy/Region of Interest</i>										
Ophthalmic										
Fetal / Obstetrics										
Abdominal										
Pediatric	P	P	P	P	P	P	P	P	P	N
Small Organ (specify)										
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	N
Adult Cephalic										
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	N
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative (specify)										
Intraoperative Neurological										
Intravascular										
Laparoscopic										


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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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription User (Per 21 CFR 801.109)

**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:

Clinical Application Anatomy/Region of Interest	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse
Ophthalmic										
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	N
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	N
Pediatric	P	P	P	P	P	P	P	P	P	N
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P	P	P	N
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	N
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	N
Exam Type, Means of Access										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative (specify)										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Nancy C. Brogdon*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number   K041552

**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:

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

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

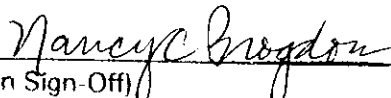
Notes: [1] Abdominal includes GYN/Pelvic;

[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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 510(k) Number       R041552      

Prescription User (Per 21 CFR 801.109)

**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:

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

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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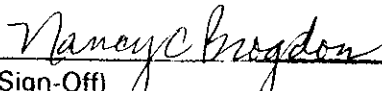
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 510(k) Number         K041552        

Prescription User (Per 21 CFR 801.109)

**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:

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

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

**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:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse		
Ophthalmic												
Fetal / Obstetrics												
Abdominal												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	N		
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transesophageal	P	P	P	P	P	P	P	P	P	N		
Transrectal												
Transvaginal												
Transurethral												
Intraoperative (specify)												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

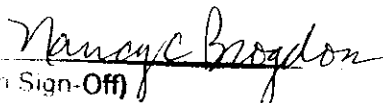
N = new indication; P = previously cleared by FDA; E = added under Appendix E

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription User (Per 21 CFR 801.109)

**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:

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

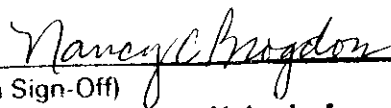
N = new indication; P = previously cleared by FDA; E = added under Appendix E

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 and Radiological Devices  
 510(k) Number K041552

**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:

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

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

Notes: [3] Cardiac is Adult and Pediatric.

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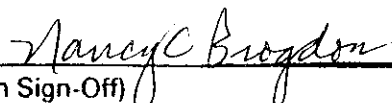
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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 2041552

Prescription User (Per 21 CFR 801.109)



**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:

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

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

Notes: [3] Cardiac is Adult and Pediatric.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription User (Per 21 CFR 801.109)

**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:

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

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

Notes: [1] Abdominal is via Intraoperative;

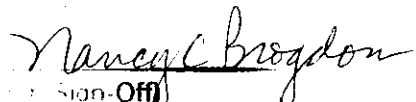
[3] Cardiac is Adult and Pediatric via Intraoperative;

[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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Sign-Off)  
 Director, Office of Reproductive and  
 Biological Devices  
 ID Number K041352

Prescription User (Per 21 CFR 801.109)

**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:

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

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription User (Per 21 CFR 801.109)

**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:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N	N	N
Abdominal	N	N	N	N	N	N	N	N	N	N	N
Pediatric	N	N	N	N	N	N	N	N	N	N	N
Small Organ (specify)											
Neonatal Cephalic											
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											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) <sup>[4]</sup>	N	N	N	N	N	N	N	N	N	N	N
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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.

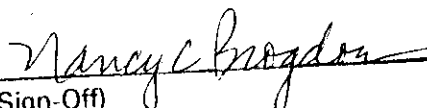
[\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition;

[3] Cardiac is Adult and Pediatric

[4] Other use includes Urology;

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