



K131514
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GE Healthcare
510(k) Premarket Notification
GE Vivid E9, May 23, 2013

JUL 12 2013

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: May 24, 2013

Submitter: GE Healthcare, GE Vingmed Ultrasound AS
Strandpromenaden 45
N-3191, Horten, Norway

Primary Contact Person: Bryan Behn
Regulatory Affairs Manager
GE Healthcare, GE Medical Systems Ultrasound and Primary
Care Diagnostics, LLC.
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Regulatory Affairs Manager
GE Vingmed Ultrasound AS
T:(+47)3302-1269
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Device: Trade Name: Vivid E9 Diagnostic Ultrasound System

Common/Usual Name: Vivid E9

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Predicate Device(s): K120201 GE Vivid E9 Diagnostic Ultrasound System
K031663 GE Vivid 7 Diagnostic Ultrasound System
K123564 GE Logiq E9 Diagnostic Ultrasound System
K120221 GE EchoPac Workstation

Device Description: GE Vivid E9 is a Track 3 diagnostic ultrasound system, which is primarily intended for cardiac imaging and analysis, but which also includes vascular and general radiology applications. The Vivid E9 incorporates a variety of electronic array transducers operating in linear, curved linear, sector/phased array or matrix array format, including two dedicated CW transducers and several real time 3D transducers. It consists of a mobile console with keyboard control panel; color LCD/TFT touch panel, LCD color video display and optional image storage and printing devices. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM capability.



Intended Use: GE Vivid E9 ultrasound system is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by, or under the direction of a qualified physician for ultrasound imaging and analysis 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).

Device Modification Overview: The following is a brief overview of the differences between the proposed Vivid E9 and the predicate Vivid E9 (K120201).

Detailed information is found in section 11 of this submission, while section 12 includes a discussion of substantial equivalence with the predicate device(s).

The modified Vivid E9 will provide users with 5 additional transducers. 4 of which are already cleared with other GE ultrasound devices, while one is new.

- The additional transducers are: M5Sc-D, C2-9-D, C1-5-D, iC5-9-D and 8C.

The subject modified Vivid E9 will also introduce two optional plug-in features originally cleared in their own right by their OEM manufacturers, TomTec and Sony Electronics.

The TomTec feature was also previously cleared for use with GE EchoPAC Workstation software for ultrasound image review, analysis and reporting (K120221).

- Mitral Valve Quantification Tool, TomTec 4D MV Assessment, K103782, is a software plug-in which will open and run in a separate window when launched on Vivid E9.
- StereoVision, visualization of real time 3D data on Sony LMD-2451MT LCD monitor, K113203, intended for 3D and 2D color video displays of clinical images.



The following modifications of existing features available on the predicate Vivid E9 will be introduced with the modified Vivid E9:

- Alternative automated ROI tracing for the Auto EF and AFI features.

The Intended Use and Indications for Use of the device have not changed by this modification.

These modifications all lead to overall quality, image enhancement and ease of use of the Vivid E9.

Technology: The Vivid E9 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output safety, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. The Vivid E9 and its applications comply with voluntary standards:

1. IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety.
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests.
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Fourth Edition.
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
7. ISO14971, Application of risk management to medical devices

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8. NEMA, Digital Imaging and Communications in
Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirement Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance Testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, Vivid E9, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid E9 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 12, 2013

GE VINGMED ULTRASOUND AS
% Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 W. Innovation Drive
WAUWATOSA WI 53226

Re: K131514
Trade/Device Name: GE Vivid E9 Diagnostic Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 1, 2013
Received: July 2, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vivid E9 Diagnostic Ultrasound Imaging System, as described in your premarket notification:

<u>Transducer Model Number</u>		
ML6-15-D	C1-5-D	3V-D
12S-D	C2-9-D	6VT-D
4V-D	9L-D	6T/6T-RS
i13L	11L-D	6Tc/6Tc-RS
iC5-9-D	M5S-D	9T/9T-RS
4C-D	M5Sc-D	P2D
8C	6S-D	P6D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure



510(k) Number (if known): K131514

Device Name: Vivid E9 Diagnostic Ultrasound System

Indications for Use:

GE Vivid E9 ultrasound system is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by, or under the direction of a qualified physician for ultrasound imaging and analysis 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).

Prescription Use: X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: N/A
(Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Vivid E9 system and for all of its probe/mode combinations. Combinations identified by "N" are new while "P" represents those previously cleared with the unmodified Vivid E9 and "P*" represents new transducers that have been previously cleared on another GE Ultrasound System. The subject modification does not alter the previously cleared system level indications, clinical applications or modes of operation.



**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 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	P
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	P
Pediatric	P	P	P	P	P	P	P	P	P	P	P
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	P
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	P
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial											
Other ^[4]	P	P	P	P	P	P	P	P	P	P	P
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	P
Transrectal	P	P	P		P	P	P	P		P	
Transvaginal	P	P	P		P	P	P	P		P	
Transurethral											
Intraoperative ^[5]	P	P	P		P	P	P	P	P	P	
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 (with or w/o color flow);

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with ML6-15-D 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											
Abdominal											
Pediatric ^[2]	P	P	P		P	P	P	P	P	P	
Small Organ ^{[1][2]}	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular ^[2]	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional ^[2]	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial											
Other											
<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: [1] Small organ includes breast, testes, thyroid.

[2] Needle guidance imaging

[*] 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 (with or w/o color flow);

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 12S-D 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											
Abdominal											
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac ^[1]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<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] Cardiac is Adult and Pediatric.

[*] 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 (with or w/o color flow);

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

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 4V-D 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	P	P	P	P	P	P	P	P	P	P	P
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	P
Pediatric	P	P	P	P	P	P	P	P	P	P	P
Small Organ											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	P
Cardiac ^[2]	P	P	P	P	P	P	P	P	P	P	P
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[3]	P	P	P	P	P	P	P	P	P	P	P
<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 renal, GYN/Pelvic
 [2] Cardiac is Adult and Pediatric.
 [3] Other use includes Urology/Prostate
 [*] 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 (with or w/o color flow);

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 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	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P	P	P	P		P	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[2]	P	P	P		P	P	P	P		P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[3]	P	P	P		P	P	P	P		P	
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] Cardiac is Adult and Pediatric via Intraoperative;

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

[*] 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 (with or w/o color flow);

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Prescription User (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with iC5-9-D 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	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P*	P*	P*		P*	P*	P*	P*		P*	
Transvaginal	P*	P*	P*		P*	P*	P*	P*		P*	
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P* = previously cleared by FDA on LOGIQ E9 (K123564); E = added under Appendix E

Notes: [4] Other use includes Urology/Prostate;

[*] 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 (with or w/o color flow);

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 4C-D 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	P	P	P		P	P	P	P	P	P	
Abdominal	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P	P	
<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.

[4] Other use includes Urology/Prostate

[*] 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 (with or w/o color flow);

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 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	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	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 ^[4]											
<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 on Vivid 7 (K031663); 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.

[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with C1-5-D 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	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Abdominal ^[1]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Pediatric	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
<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 on LOGIQ E9 (K123564); E = added under Appendix E

- Notes: [1] Abdominal includes Renal, GYN/Pelvic.
 [2] Small organ includes breast, testes, thyroid.
 [4] Other use includes Urology/Prostate
 [*] 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 (with or w/o color flow);

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with C2-9-D 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*	P*	
Abdominal ^[1]	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	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
<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 on LOGIQ E9(K123564); E = added under Appendix E

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

[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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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 9L-D 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											
Abdominal											
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial											
Other ^[4]											
<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.

[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 11L-D 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											
Abdominal											
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]	P	P	P		P	P	P	P	P	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.

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

[*] 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 (with or w/o color flow);

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with M5S-D 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	P	P	P	P	P	P	P	P	P	P	
Abdominal	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P	P	P	P	P	P	P	P	
<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.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[*] 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 (with or w/o color flow);

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**Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with M5Sc-D 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	
Abdominal	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	
Cardiac ^[3]	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	N	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: [2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[*] 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 (with or w/o color flow).

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 6S-D 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	P	P	P	P	P	P	P	P	P	P	
Abdominal	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ ^[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<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.

[3] Cardiac is Adult and Pediatric.

[*] 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 (with or w/o color flow);

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 3V-D 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	P	P	P	P	P	P	P	P	P	P	P
Abdominal	P	P	P	P	P	P	P	P	P	P	P
Pediatric	P	P	P	P	P	P	P	P	P	P	P
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	P
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	P
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P	P	P	P	P	P	P	P	P
<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.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[*] 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 (with or w/o color flow);

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 6VT-D 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	P
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	P	P
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.
 [*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 6T/6T-RS 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	
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	P	
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.
[*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 6Tc/6Tc-RS 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	
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	P	
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.
 [*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 with 9T/9T-RS 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]	P	P	P	P	P	P	P	P	P	P	
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	P	
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

[*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 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	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]			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.

[*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 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	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]			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.

[*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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(Division Sign-Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

510(k): K131514