K121063

510(k) Summary

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

AUG 2 1 2012

Date:	5 April 2012
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare, [GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC] T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Carmel Lehrer Regulatory Affairs Specialist GE Medical Systems Israel Ltd. T:+972-4-8419-534 F:+972-4-8419-500
Device: Trade Name:	Vivid S5 and Vivid S6 Diagnostic Ultrasound System
Common/Usual Name:	Vivid S5, Vivid S6
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Predicate Device(s):	Vivid S5 and Vivid S6 Diagnostic Ultrasound Systems, K102393. Vivid E9 Diagnostic Ultrasound System, K101149.
Device Description:	The Vivid S5 and Vivid S6 are mobile ultrasound consoles having a wide assortment of electronic array transducers intended primarily for echocardiography with additional capability in vascular and general ultrasound imaging. Its intuitive user interface, high level of auto-optimization along with significantly reduced size and weight make it readily maneuverable, efficient and easy to use.
Intended Use:	The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics; Abdominal/Gynecology; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal; Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, and vascular).

Technology: The modified Vivid S5/S6 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, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The modified Vivid S5/S6 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

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

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, the modified Vivid S5/S6, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the modified Vivid S5/S6 to be as safe, and effective as the predicate device(s). The performance of the modified Vivid S5/S6 is substantially equivalent to the predicate device(s).

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, and ISO13485 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 Healthcare that the Vivid S5/S6 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 21 2012

GE Medical Systems Israel Ltd.
% Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K121063
Trade/Device Name: Vivid S5/S6
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, and LLZ
Dated: August 10, 2012
Received: August 13, 2012

Dear Mr. Behn:

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 Vivid S5/S6, as described in your premarket notification:

Transducer Model Number

3S-RS	10S-RS	E8C-RS	6Tc/6Tc-RS
3Sc-RS	12S-RS	8L-RS	6T/6T-RS
5S-RS	M4S-RS	9L-RS	9T/9T-RS
6S-RS	4C-RS	12L-RS	P2D
7S-RS	8C-RS	i12L-RS	P6D

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 895. 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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known):

Device Name: Vivid S5/S6

Indications for Use:

The current modifications do not change the indications for use. As previously reported and cleared, the Vivid S5/S6 ultrasound systems are intended for use by, or under the direction of, a qualified physician for ultrasound imaging and analysis in Fetal/Obstetrics; Abdominal/GYN; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal; Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, and vascular).

Prescription Use___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K121063

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Vivid S5/S6 system and for all of its probe/mode combinations. Combinations identified by "P" represent those previously FDA cleared. In a similar manner "N" represents a new mode or application being added as new to the system or a transducer in this submission. In a similar manner, "E" represents combinations added to the unmodified device via Guidance Appendix E. This modification did not alter the previously cleared system level indications, clinical applications or modes of operation.

Indications for Use tables' headings, legends and footers taken from all previous submissions, are aligned to the same unified format.

Pencil probes

PW mode of operation, which was previously included in error for the Pencil probes; P2D and P6D, has been removed from their Indications for Use forms.

12S-RS

The 12S-RS is identical to the 12S-D previously cleared on the Vivid E9 K101149 with a change to the -RS laptop/small console connector instead of the -D large console connector. Clinical applications and modes of operation are as in 12S-D. Additional Abdominal and Peripheral Vascular applications are added to 12S-RS based on clearance of these applications on other transducers (10S-RS and 7S-RS) previously cleared on Vivid S5/S6 (K071985, K092079) and Vivid i/q (K082374).

Transducers added via Appendix E: 3Sc-RS

One transducer has been added via Appendix E of the Ultrasound Guidance since the previous clearance. Transducer 3Sc-RS, which is similar to the previously cleared 3S-RS with a few minor improvements.

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 Diagnostic Ultrasound System

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	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)[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	
Cardiac[3]	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	P	P	P		P	P	P	P	P	P	
Other[4]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P		P	P	P	P	P	P	
Transvaginal	P	P	P		P	P	P	P	P	P	
Transuretheral											
Intraoperative (specify)[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 GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division of Radiological Devices
OIVD

Prescription Use (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 3S-RS 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	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[2]	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	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[3] Other use includes Urology.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Division of Radiological Devices
OIVD

Prescription Use (Per 21 CFR 801.109)

510k K121063

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 3Sc-RS 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	E	E	E	E	E	E	E	E	E	E	
Abdominal[1]	E	E	E	E	E	E	E	E	E	E	
Pediatric	E	E	E	E	E	E	E	E	E	E	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	E	E	E	E	
Cardiac[2]	E	E	E	E	E	E	E	E	E	E	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[3]	E	E	E	E	E	E	E	E	E	E	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[3] Other use includes Urology.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Prescription Use (Per 21 CFR 801.109) Division of Radiological Devices

510k K121063 OIVD

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 5S-RS 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	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[2]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 6S-RS 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	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac[2]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109) **(Division Sign-Off)**
Division of Radiological Devices
OIVD

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 7S-RS 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											
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac[2]	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											
Musculo-skeletal Superficial											
Other[3]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[3] Other use includes Urology.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 10S-RS 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											
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[2]	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											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 12S-RS 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											
Abdominal[1]	N	N	N	N	N	N	N	N	N		
Pediatric	N	N	N	N	N	N	N	N	N		
Small Organ (specify)											
Neonatal Cephalic	N	N	N	N	N	N	N	N	N		
Adult Cephalic											
Cardiac[2]	N	N	N	N	N	N	N	N	N		
Peripheral Vascular	N	N	N	N	N	N	N	N	N		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.

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OIVD

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with M4S-RS 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	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[2]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 4C-RS 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[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[2]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Other use includes Urology.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 8C-RS 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											
Abdominal[1]	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ (specify)[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac[3]	P	P	P		P	P	P	P	P	P	
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with E8C-RS 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[1]	P	P	P		P	P	P	P	P	P	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[2]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P	P	
Transvaginal	P	P	P		P	P	P	P	P	P	
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Other use includes Urology.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 8L-RS 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											
Abdominal[1]	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ (specify)[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	P	P	P		P	P	P	P	P	P	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 9L-RS 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											
Abdominal[1]	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ (specify)[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	P	P	P		P	P	P	P	P	P	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 12L-RS 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											
Abdominal	P*	P*	P*		P*	N	P*	P*	P*	P*	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ (specify)[1]	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	P	P	P		P	P	P	P	P	P	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[2]	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 (*Previously Cleared K113690)

Notes:
[1] Small organ includes breast, testes, thyroid.
[2] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with i12L-RS 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											
Abdominal[1]	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ (specify)[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P	P	P		P	P	P	P	P	P	
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	P	P	P		P	P	P	P	P	P	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[4]	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 GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 6Tc/6Tc-RS 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[1]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal											
Transvaginal											
Transuretheral											
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/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.
[**] 6Tc differs from 6Tc-RS only in the connector type

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 6T/ 6T-RS 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[1]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal											
Transvaginal											
Transuretheral											
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/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.
[**] 6T differs from 6Tc-RS only in the connector type

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 9T/ 9T-RS 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[1]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal											
Transvaginal											
Transuretheral											
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/CWD, B/Color/PWD, B/Power/PWD.
[♦] Coded Pulse is for digitally encoded harmonics.
[**] 9T differs from 9T-RS only in the connector type

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with P2D 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[1]				**P**							
Peripheral Vascular				**P**							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Cardiac is Adult and Pediatric.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with P6D 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											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[1]				P							
Peripheral Vascular				P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:
[1] Cardiac is Adult and Pediatric.

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