NOV - 5 2010

K102393

Section 5 — 510(k) Summary

Vivid S5/S6

510(k) Summary

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

Date:	18 August 2010
Submitter:	GE Healthcare [GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC] 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 GE Healthcare
Secondary Contact Person:	Jim Turner Regulatory Affairs Manager America's Service GE Healthcare, [GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC] T:(262) 544-3359 F:(414)908-9225
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 Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	Vivid S5 and Vivid S6 Diagnostic Ultrasound Systems, K092079 currently in commercial distribution.
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.

Comparison with the predicate device shows the modified Vivid S5/S6 is of a comparable type and substantially equivalent to the current Vivid S5/S6. It has the same overall characteristics, key safety and effectiveness features, physical design, construction, and materials, and has the same intended uses and operating modes as the predicate device. The modified Vivid S5/S6 has additional software features that are similar to other cleared GE Ultrasound systems.

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

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Drive
WAUWATOSA WI 53226

NOV - 5 2010

Re: K102393
Trade/Device Name: Vivid S5 and Vivid S6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: October 4, 2010
Received: October 5, 2010

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 and Vivid S6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

6Tc/6Tc-RS
6T/6T-RS
9T/9T-RS
6T-RS

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 Jana Delfino at (301) 796-6503.

Sincerely yours,

David G. Brown, Ph.D.
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

K102393

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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__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_ (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 K102393

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 Diagnostic Ultrasound System

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	**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											
Intracardiac and Intraluminal											
Laparoscopic											

N = new indication; **P** = previously cleared by FDA on Vivid S5/S6 (K071985); **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/PWD, B/Color/PWD, B/Power/PWD, B/Color M
[♦] Coded Pulse is for digitally encoded harmonics..

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510K K102393

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

Prescription User (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											
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)											
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; (Transducer previously cleared on Vivid S5/S6 (K092079));

E = added under Appendix E

Notes:

[3] Cardiac is Adult and Pediatric.

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

[♦] Coded Pulse is for digitally encoded harmonics.

[**] 6Tc-RS is cleared on Vivid S5/S6 BT10 (K092079). 6Tc differs from 6Tc-RS only in the connector type.

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

Prescription User (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:

	Mode of Operation										
Clinical Application **Anatomy/Region of Interest**	**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[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; **P** = previously cleared by FDA (Transducer previously cleared on Vivid S5/S6 (K071985);
E = added under Appendix E

Notes:
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.
[**] Due to a Typo, probe 6T was not listed in this form's heading in K071985. The probe is included in Vivid S5/S6 K071985 (see Table 2.3.3 – Transducer Characteristics Summary and Special Report)

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Prescription User (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:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	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[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
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,(Transducer previously cleared on Vivid S5/S6 (K071985);
E = added under Appendix E

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Division of Radiological Devices
Diagnostic Device Evaluation and Safety
K102393

Notes:
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.
[**] Due to a Typo, probe 6T was not listed in this form's heading in K071985. The probe is included in Vivid S5/S6 K071985 (see Table 2.3.3 – Transducer Characteristics Summary and Special Report)

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Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Vivid S5/S6 -with 6T-RS Transducer

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

	Mode of Operation										
Clinical Application *Anatomy/Region of Interest*	B	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[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; **P** = previously cleared by FDA, (Transducer previously cleared on Vivid S5/S6 (K071985);
E = added under Appendix E

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510K K102393

Notes:
[3] Cardiac is Adult and Pediatric.
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦]Coded Pulse is for digitally encoded harmonics.
[**] Due to a Typo, probe 9T was not listed in this form's heading in K071985. The probe is included in Vivid S5/S6 K071985 (see Table 2.3.3 – Transducer Characteristics Summary and Special Report)

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