K101149
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Special 510(k) Premarket Notification
GE Vivid E9 BT10 Ultrasound System
April 21, 2010

OCT 13 2010

Attachment B

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

Section a):

1. Submitter: GE Healthcare
9900 W Innovation Dr., RP-2138
Wauwatosa, WI 53226
USA

Contact Person: Bryan Behn
Regulatory Affairs Manager
Telephone: 414-721-4214; Fax: 414-918-8275

Date Prepared: April 21, 2010

2. Device Name: GE Vivid E9 Diagnostic Ultrasound System
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

3. Marketed Devices: GE Vivid E9 Ultrasound System, K081921, and GE Logiq E9 Ultrasound System, K092271, currently in commercial distribution.

4. Device Description: The GE Vivid E9 Diagnostic Ultrasound is a full-featured echocardiography imaging and analysis system with additional capability in vascular and general ultrasound imaging. It consists of a mobile console with multiple electronic array transducers that provide digital acquisition, processing and display capability. The user interface includes a floating and variable height user control panel with specialized controls, high-resolution LCD display and separate LCD touch panel. This modification offers improved performance and productivity for users.

5. Indications for Use: The 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).

6. Comparison with Predicate Device: The GE Vivid E9 BT10 is of a comparable type and substantially equivalent to the current GE Vivid E9 with enhanced performance and added transducers; 4V-D, 12S-D, ML6-15-D and i13L, which are new to GE Vivid E9. It has the same overall characteristics, key safety and effectiveness features, physical design, general overall construction, materials, and has the same intended uses and operating modes as the predicate device. The additional software features are similar to other cleared GE Ultrasound systems like GE Logiq E9.

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Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility as well as thermal, electrical and mechanical safety, and has been found to conform with applicable and harmonized medical device safety standards.
2. Clinical Tests: None required.
3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2008 and ISO13485:2003 quality systems. The device conforms to applicable medical device safety standards. Compliance is verified through 3rd party product certifications and regular production monitoring. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE Vivid E9 Diagnostic Ultrasound system 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
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

GE Vingmed Ultrasound AS
% Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 W Innovation Dr., RP-2138
WAUWATOSA WI 53226

OCT 13 2010

Re: K101149
Trade/Device Name: GE Vivid E9 BT10 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: August 27, 2010
Received: August 30, 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 GE Vivid E9 BT10 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

ML6-15-D
12S-D
4V-D
i13L

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)

K101149

Special 510(k) Premarket Notification
GE Vivid E9 BT10 Ultrasound System
April 21, 2010

Diagnostic Ultrasound Indications for Use Form

GE Vivid E9 BT10 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	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
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	
Transvaginal	P	P	P		P	P	P	P		P	
Transuretheral											
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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription User (Per 21 CFR 801.109) 510K K101149

K101149

Special 510(k) Premarket Notification
GE Vivid E9 BT10 Ultrasound System
April 21, 2010

Diagnostic Ultrasound Indications for Use Form

GE Vivid E9 BT10 with ML6-15-D 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	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric[2]	N	N	N		N	N	N	N	N	N	
Small Organ[1][2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic	N	N	N		N	N	N	N	N	N	
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular[2]	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Conventional[2]	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, (Transducer previously cleared on GE LOGIQ E9 BT08 (K073408)); 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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510K K101149

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Special 510(k) Premarket Notification
GE Vivid E9 BT10 Ultrasound System
April 21, 2010

Diagnostic Ultrasound Indications for Use Form

GE Vivid E9 BT10 with 12S-D Transducer

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

Clinical Application	Mode of Operation										
Anatomy/Region of Interest	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	N	N	N	N	N	N	N	N	N	N	
Small Organ											
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	
Adult Cephalic											
Cardiac[1]	N	N	N	N	N	N	N	N	N	N	
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] 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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Prescription User (Per 21 CFR 801.109)

510K K101149

K101147

Special 510(k) Premarket Notification
GE Vivid E9 BT10 Ultrasound System
April 21, 2010

Diagnostic Ultrasound Indications for Use Form

GE Vivid E9 BT10 with 4V-D 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	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N	N	N
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	N
Pediatric	N	N	N	N	N	N	N	N	N	N	N
Small Organ											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	N
Cardiac[2]	N	N	N	N	N	N	N	N	N	N	N
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[3]	N	N	N	N	N	N	N	N	N	N	N
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal includes 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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Prescription User (Per 21 CFR 801.109)

K101149

Diagnostic Ultrasound Indications for Use Form
GE Vivid E9 BT10 with i13L 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	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N	N	N	N		N	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[2]	N	N	N		N	N	N	N		N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative[3]	N	N	N		N	N	N	N		N	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, (Transducer previously cleared on GE System FIVe (K001267)); 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.

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