DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

March 4, 2015

Re: K150087
Trade/Device Name: Vivid E80, Vivid E90 and Vivid E95 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 13, 2015
Received: January 15, 2015

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.

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150087

Device Name
Vivid E80 and Vivid E90 and Vivid E95

Indications for Use *(Describe)*
The device 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/Obstetrics; 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).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 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	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[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	N
Cardiac[3]	N	N	N	N	N	N	N	N	N	N	N
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial											
Other[4]	N	N	N	N	N	N	N	N	N	N	N
Exam Type, Means of Access											
Transesophageal	N	N	N	N	N	N	N	N	N	N	N
Transrectal	N	N	N		N	N	N	N		N	
Transvaginal	N	N	N		N	N	N	N		N	
Transuretheral											
Intraoperative[5]	N	N	N		N	N	N	N	N	N	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (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 In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with 12S-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	**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											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 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	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
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with iC5-9-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	**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**	
Exam Type, Means of Access											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**	**P**	**P**	**P**		**P**	
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**		**P**	
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with 8C 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]	**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]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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);

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

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with C2-9-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	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**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with 9L-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	**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]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with 11L-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	**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]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative[5]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with M5Sc-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	**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**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with 6S-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	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]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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);

(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)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with C1-6-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	**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**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid S60/S70 (K142323)

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)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with L8-18i-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[1]											
Pediatric	**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**	
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]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative [5]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Logiq E9 (K142160)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[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, 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) Page 13 of 18

Diagnostic Ultrasound Indications for Use Form

GE Vivid E80 / Vivid E90 / Vivid E95 with 6VT-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											
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)											
Exam Type, Means of Access											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 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	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)											
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											

P = previously cleared by FDA on Vivid E9 (K131514)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 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	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)											
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											

P = previously cleared by FDA on Vivid E9 (K131514)

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)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 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	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)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

P = previously cleared by FDA on Vivid E9 (K131514)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 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	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)											
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: [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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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

510(k) Summary

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

Date:	January 13, 2015
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. T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Jan Tore Thollefsen Regulatory Affairs Manager GE Vingmed Ultrasound AS T:(+47)3302-1269 F:(+47)3302-1357
Device: Trade Name:	Vivid E80, Vivid E90, Vivid E95 Diagnostic Ultrasound System
Common/Usual Name:	Vivid E80, Vivid E90, Vivid E95
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):	K1315141 GE Vivid E9 Diagnostic Ultrasound System K142323 GE Vivid S60/S70 Diagnostic Ultrasound System K142160 L8-18i-D Diagnostic Ultrasound Transducer on Logiq E9.
Device Description:	GE Vivid E80 / E90 / E95 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 E80 / E90 / E95 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, Alternative OLED or 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 E80 / E90 / E95 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/Obstetrics; 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).

Technology: The Vivid E80 / E90 / E95 employ the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Comparison to predicate

The Vivid E80/E90/E95 systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

	Proposed Device Vivid E80/E90/E95	**Predicate Device Vivid E9 (K131514)**
Indications and Clinical Applications:		
• Fetal/Obstetrics;	✓	✓
• Abdominal (Including Renal & Gyn)	✓	✓
• Pediatric	✓	✓
• Small Organ (breast, testes, thyroid);	✓	✓
• Neonatal Cephalic;	✓	✓
• Adult Cephalic;	✓	✓
• Cardiac (adult and pediatric);	✓	✓
• Peripheral Vascular;	✓	✓
• Musculo-skeletal Conventional	✓	✓
• Urology (including prostate);	✓	✓
• Transesophageal;	✓	✓
• Transrectal (TR);	✓	✓
• Transvaginal (TV);	✓	✓
• Intraoperative (abdominal, thoracic, & vascular).	✓	✓

Transducer Arrays:	**Proposed Device Vivid E80/E90/E95**	**Predicate Device Vivid E9 (K131514)**
Matrix Phased Array (incl single crystal)	✓	✓
Phased Array	✓	✓
Linear Array	✓	✓
Curved Array	✓	✓
Pencil (Doppler)	✓	✓
Ultrasound Modes:	**Proposed Device Vivid E80/E90/E95**	**Predicate Device Vivid E9 (K131514)**
B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power	✓ ✓	✓ ✓
Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.	✓ ✓ ✓	✓ ✓ ✓
Harmonic	✓	✓
Coded Pulse	✓	✓
Real-time 3D & Multi-plane.	✓	✓
Processing & Display features:	**Proposed Device Vivid E80/E90/E95**	**Predicate Device Vivid E9 (K131514)**
Image mapping (color & gray)	✓	✓
Time/ spatial filtering and enhancement,	✓	✓
TGC, TVI, SI/SRI, TSI, TSI w/ surface	✓	✓
rendering, Harmonic Imaging,	✓	✓
Pulsatile-Flow, B-Flow, Extended FOV,	✓	✓
Tissue Tracking,	✓	✓
Real-time 3D and Multi-plane processing,	✓	✓
Real-time 3D Color Flow,	✓	✓
Blood Flow Imaging (BFI), Spatial	✓	✓
Compounding / Speckle Reduction	✓	✓
imaging, Slice View, Laser-Lines,	✓	✓
Continuous Tissue Optimization (CTO)		
Automated Functional Imaging (AFI) w/	✓	✓
Bull's Eye display, Triplane AFI.	✓	✓
LCD display, StereoVision,	✓	✓
2D Stress, Multiplane Stress	✓	✓
HDLive, Virtual Apex, 4D Auto AVQ	✓	
OLED display	✓ Alternative to LCD	LCD display only
Processing & Display features: (Continued)	**Proposed Device Vivid E80/E90/E95**	**Predicate Device Vivid S60/S70 (K142323)**
AFI Stress, Smart Depth, Virtual Apex, 4D Stress.	✓	✓
Standards Compliance:	**Proposed Device Vivid E80/E90/E95**	**Predicate Device Vivid E9 (K131514)**
Designed and verified to meet harmonized standards for Electrical Safety, EMC, Biocompatibility. Software Life Cycle Management, Risk Management and Usability.	✓	✓
Track 3 (within FDA limits)	✓	✓

Transducers:	Proposed Device Vivid E80/E90/E95	Predicate Device Vivid E9 (K131514)
• M5Sc-D	✓	✓
• 6S-D	✓	✓
• 12S-D	✓	✓
• 6VT-D	✓	✓
• 6Tc	✓	✓
• 6Tc -RS	✓	✓
• 9T	✓	✓
• 9T -RS	✓	✓
• 9L-D	✓	✓
• 11L-D	✓	✓
• 8C	✓	✓
• P2D	✓	✓
• P6D	✓	✓
• 4V-D	✓	✓
• iC5-9-D	✓	✓
• C2-9-D	✓	✓
Transducers: (Continued)	**Proposed Device Vivid E80/E90/E95**	**Predicate Device Vivid S60/S70 (K142323)**
• C1-6-D	✓	✓
Transducers: (Continued)	**Proposed Device Vivid E80/E90/E95**	**Predicate Device Logiq E9 (K142160)**
• L8-18i-D	✓	✓

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 E80 / E90 / E95 and its applications comply with voluntary standards:

1. ANSI/AAMI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance.
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility Requirements and Tests.
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the basic safety and essential performance 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
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 E80 / E90 / E95, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid E80 / E90 / E95 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).