



GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Ms. Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

November 2, 2017

Re: K173341
Trade/Device Name: Vivid E80, Vivid E90, Vivid E95
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 24, 2017
Received: October 25, 2017

Dear Ms. Ortiz:

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 (DICE) 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 (DICE) 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,

 For

Robert Ochs, Ph.D.

Director

Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173341

Device Name

Vivid E80

Vivid E90

Vivid E95

Indications for Use (Describe)

Vivid E80 / Vivid E90 / Vivid E95 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; Musculo-skeletal Superficial; 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Vivid E80, Vivid E90 and Vivid E95. Combinations identified “P” represents those previously cleared with another GE Ultrasound system. Combinations identified as “N” are new.

The following Indication for Use forms are appended:

System: Vivid E80 / Vivid E90 / Vivid E95

Transducer: C3-10-D

Transducer: 12S-D

Transducer: 4V-D

Transducer: 4Vc-D

Transducer: iC5-9-D

Transducer: 8C

Transducer: C2-9-D

Transducer: 9L-D

Transducer: 11L-D

Transducer: M5Sc-D

Transducer: 6S-D

Transducer: C1-6-D

Transducer: L8-18i-D

Transducer: 6VT-D

Transducer: 6Tc

Transducer: 6Tc-RS

Transducer: 9T

Transducer: 9T-RS

Transducer: 10T-D

Transducer: P2D

Transducer: P6D



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[6,8,9,11]
Abdominal	P	P	P	P	P	P	P	P	P	P	[1,6,8,9,10]
Pediatric	P	P	P	P	P	P	P	P	P	P	[6,8,9]
Small Organ	P	P	P		P	P	P	P	P	P	[2,8]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[8,9]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[6,9]
Cardiac	P	P	P	P	P	P	P	P	P	P	[3,6,9]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	[8]
Other	P	P	P	P	P	P	P	P	P	P	[4,6,8,9]
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[6,9]
Transrectal	P	P	P		P	P	P	P		P	[8]
Transvaginal	P	P	P		P	P	P	P		P	[8]
Transurethral											
Intraoperative	P	P	P		P	P	P	P	P	P	[5,8]
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8,9]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Vivid E80 / Vivid E90 / Vivid E95 with C3-10-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P		P	P	P	P	P	P	[8]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ											
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[8]
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P	P	P	P	P	P	P	P	[9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[9]
Small Organ											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[3,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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

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Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[6,9,11]
Abdominal	P	P	P	P	P	P	P	P	P	P	[1,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[6,9]
Small Organ											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[6,9]
Cardiac	P	P	P	P	P	P	P	P	P	P	[3,6,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P	P	P	P	P	P	P	P	[4,6,9]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Vivid E80 / Vivid E90 / Vivid E95 with 4Vc-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N	N	[6,9,11]
Abdominal	N	N	N	N	N	N	N	N	N	N	[1,6,9]
Pediatric	N	N	N	N	N	N	N	N	N	N	[6,9]
Small Organ											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	[6,9]
Cardiac	N	N	N	N	N	N	N	N	N	N	[3,6,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	N	N	N	N	N	N	N	N	N	N	[4,6,9]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	N	N	N	N	N	N	N	N	N	N	[9]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	[8,11]
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P		P	P	P	P	P	P	[4,8]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P	P	P		P	P	P	P		P	[8]
Transvaginal	P	P	P		P	P	P	P		P	[8]
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P		P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P		P	[8]

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
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 - [5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P		P	P	P	P	P	P	[1,8,10]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ (specify)	P	P	P		P	P	P	P	P	P	[8]
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[8]
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[8]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
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 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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(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)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	[8,11]
Abdominal	P	P	P		P	P	P	P	P	P	[1,8,10]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P		P	P	P	P	P	P	[4,8]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P		P	P	P	P	P	P	[8]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ	P	P	P		P	P	P	P	P	P	[2,8]
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ	P	P	P		P	P	P	P	P	P	[2,8]
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative	P	P	P		P	P	P	P	P	P	[5,8]
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



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510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[9,11]
Abdominal	P	P	P	P	P	P	P	P	P	P	[9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[9]
Small Organ											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Cardiac	P	P	P	P	P	P	P	P	P	P	[3,9]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P	P	P	P	P	P	P	P	[4,9]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P	P	P	P	P	P	P	P	[9]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



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510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[9,11]
Abdominal	P	P	P	P	P	P	P	P	P	P	[9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[9]
Small Organ											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[3,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)

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510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	[8,11]
Abdominal	P	P	P		P	P	P	P	P	P	[1,8]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P		P	P	P	P	P	P	[4,8]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



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510(k) Premarket Notification Submission

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 <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ	P	P	P		P	P	P	P	P	P	[2,8]
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[8]
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative	P	P	P		P	P	P	P	P	P	[5,8]
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[6,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[6,9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

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)

[6] 3D/4D Imaging mode

[7] Includes image guidance for freehand needle placement

[8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD

[9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

[10] Abdominal includes Aorta-Iliac Artery

[11] Fetal/Obstetrics includes Fetal Heart

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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[3,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form GE Vivid E80 / Vivid E90 / Vivid E95 with 10T-D Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	N	N	N	N	N	N	N	N	N	N	[3,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	N	N	N	N	N	N	N	N	N	N	[9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

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)

[6] 3D/4D Imaging mode

[7] Includes image guidance for freehand needle placement

[8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD

[9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

[10] Abdominal includes Aorta-Iliac Artery

[11] Fetal/Obstetrics includes Fetal Heart

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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac			P	P							[3]
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



GE Healthcare

510(k) Premarket Notification Submission

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 <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac			P	P							[3]
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Interventional Guidance											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid E80/Vivid E90/Vivid E95 (K170823); N = New indication

- 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)
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Abdominal includes Aorta-Iliac Artery
 - [11] Fetal/Obstetrics includes Fetal Heart

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)



GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

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

Date: October 23, 2017

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Tracey Ortiz
Regulatory Affairs Director
GE Healthcare
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Secondary Contact Person: Jan Tore Thollefsen
Regulatory Affairs Manager
GE Vingmed Ultrasound AS

Device: Trade Name: Vivid E80, Vivid E90, Vivid E95
Common/Usual Name: Diagnostic Ultrasound System
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

Primary Predicate Device: Vivid E80, Vivid E90, Vivid E95 (K170823)

Device Description: Vivid E80 / Vivid E90 / Vivid E95 systems are Track 3 diagnostic ultrasound systems primarily intended for cardiac imaging and analysis, but which also includes vascular and general radiology applications. The Vivid E80 / Vivid E90 / Vivid 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. Vivid E80 will support 2D imaging, while Vivid E90 and Vivid E95 will support real time 3D imaging in addition to 2D, and incorporate several real-time 3D transducers. Vivid E80 / Vivid E90 / Vivid 95 consists of a mobile console with keyboard control panel; color LCD/TFT touch panel, OLED color video display, DVI connector for optional external video display, and optional image storage and printing devices. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM capability.



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Intended Use: Vivid E80 / Vivid E90 / Vivid E95 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; Musculo-skeletal Superficial; Urology (including prostate), Transesophageal; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

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

Determination of Substantial Equivalence: Comparison to Predicate Devices
The Vivid E80 / Vivid E90 / Vivid E95 systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- A new transducer, “4Vc-D”, was added for use with regular 2D and 4D imaging. The 4Vc-D is a matrix array transducer which is built on design principles from the predicate 4V-D, already cleared for use with Vivid E80, Vivid E90 and Vivid E95 (K170823). 4Vc-D has reduced physical dimensions and weight compared to the predicate 4V-D, and has identical indications for use.
- A new transducer, “10T-D”, was added for use with transesophageal pediatric or adult imaging. 10T-D has the same indications for use as the predicate 9T transducer already cleared with Vivid E80, Vivid E90 and Vivid E95 (K170823).
- A new “Vmax” option was added to offer a high performance Graphical Processing Unit (GPU) as an alternative to the standard GPU used in the predicate Vivid E80 / Vivid E90 / Vivid E95. This new GPU will provide a higher processing speed of the receiving ultrasound information, and thus enable higher 4D volume-rates in imaging.



Summary of Non-Clinical

Tests:

Vivid E80 / Vivid E90 / Vivid E95 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 comply with applicable medical device safety standards. The Vivid E80 / Vivid E90 / Vivid E95 complies with voluntary standards:

- ANSI / AAMI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/A1:2012
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2007.
- 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, 2007-08.
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, 2004
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- IEC62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2010
- ISO14971, Application of risk management to medical devices, 2007
- NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2016

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

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



GE Healthcare

510(k) Premarket Notification Submission

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests: The subject of this premarket submission, Vivid E80 / Vivid E90 / Vivid E95, did not require clinical studies to support substantial equivalence.

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