



GE Medical Systems Ultrasound and Primary Care Diagnostics
Tracey Ortiz
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

October 25, 2018

Re: K181685

Trade/Device Name: Vivid E80, Vivid E90, Vivid E95
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, ITX, IYO
Dated: October 8, 2018
Received: October 9, 2018

Dear Tracey 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D.

O'hara -S

Digitally signed by Michael D.
O'hara -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
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Date: 2018.10.25 17:39:35 -04'00'

For

Robert A. 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)

K181685

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.

There are no changes to the Indications for Use compared to the predicate Vivid E95 / Vivid E90 / Vivid E80 (K173341)

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.

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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 <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

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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 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
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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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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	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	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

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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
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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 <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]

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- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
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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
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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 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:
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Diagnostic Ultrasound Indications for Use Form
GE Vivid E80 / Vivid E90 / Vivid E95 with C2-9-D Transducer

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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.

(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 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.

(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 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)



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)



GE Healthcare
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)

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 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)



GE Healthcare
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.

(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 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)



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)



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)



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	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.

(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 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)



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)											
<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)



510(k) Summary

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

Date: October 5, 2018

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
T:(262) 676-6120

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 (K173341)

Secondary Predicate Device(s): LOGIQ E9 (K082185)

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, an OLED or LCD 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.



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.

- The new feature “CT Fusion” is added as an imaging tool to allow the user to view aligned Computed Tomography and 4D Ultrasound data simultaneously on the Vivid E95 scanner. CT Fusion in Vivid E95 is substantially equivalent to the V Nav feature with Fusion on LOGIQ E9 (K082185).
- The new feature “4D Marker” allows the user to manually place annotations/markers into 3D/4D datasets on Vivid E95, and on Vivid E90 when upgraded to 4D. This is an extension of existing image annotation capabilities on the predicate Vivid E90 / Vivid E95 (K173341).
- The new features “4D Auto LAQ” is a new feature for quantification of Left Atrium volumes, emptying fraction and strain in live 3D (4D). The feature is substantially equivalent to the 4D Auto RVQ already present on the predicate Vivid E80 / Vivid E90 / Vivid E95 (K173341).
- “AutoEF 2.0” is a workflow improvement of functionality already available on the predicate Vivid E80 / Vivid E90 / Vivid E95 (K173341).
- “AFI 2.0” is a workflow improvement of functionality already available on the predicate Vivid E80 / Vivid E90 / Vivid E95 (K173341). In addition to the changes to the tool, we have now expanded it for pediatric use.



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- “Automatic View Recognition” is new functionality based on deep neural network embedded into the software of Vivid E95 / Vivid E90. Automatic View Recognition is a tool for workflow improvement to AFI 2.0 and Auto EF 2.0 and provides an automated alternative to manual image selection already available on the predicate Vivid E80 / Vivid E90 / Vivid E95 (K173341).
- With the subject submission references to two new studies for Z-score values are added to the “Z Score” functionality available on the predicate Vivid E80 / Vivid E90 / Vivid E95 (K173341).
- “Stream Server” functionality is added for streaming 2D and 4D ultrasound data real time over LAN or WLAN network connection, using secure authentication and encryption. The functionality is enabled by the ultrasound operator and is for visualization of ultrasound images to a remote reviewer. The feature is an augmentation of the capabilities of the previously cleared predicate (K173341) allowing remote viewing.
- “Tricefy Uplink” is available with the subject Vivid E80 / Vivid E90 / Vivid E95 enabling a new dataflow to Tricefy Cloud service offered by Trice Imaging Inc.
- The software features of the subject Vivid E80 / Vivid E90 / Vivid E95 are installed and are running under Windows 10 Embedded Operating software environment. This is substantially equivalent to the cleared Vivid E80 / Vivid E90 / Vivid E95 (K173341) where the software features were installed and were running under Windows 7 Embedded.
- “Whitelisting” is implemented on the subject Vivid E80 / Vivid E90 / Vivid E95. White listing is a cyber security technology available with Windows 10 Embedded, and is implemented as additional protection against running and infecting the ultrasound system with malware. The addition of “Whitelisting” will have no impact on the safety or effectiveness of the clinical functionality of the Vivid systems.
- “Texture”, an imaging technique for enhancement of structural information and attenuation of reverberations, was added. Texture supplements traditional B-Mode imaging and can be toggled on/off from QuickApps control



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panel. Texture has no impact on the safety or effectiveness of the Vivid systems.

- “Hybrid Filter”, a post processing image algorithm for B-mode imaging, was added. Hybrid filter is controlled from the control panel and is designed to enhance strong structures in the image without affecting subtle image information. Hybrid Filter has 3 settings Off / Mild / Strong per user preference and has no impact on the safety or effectiveness of the Vivid Systems.
- A 24” LCD monitor is added as an alternative to the 22” OLED monitor cleared with the predicate Vivid E80 / Vivid E90 / Vivid E95 (K173341). The change has no impact on safety or effectiveness of the devices.
- The weight of Vivid E80 / Vivid E 90 / Vivid E95 was reduced from 126 Kg to 120 Kg due to re-configuration and re arrangement of internal parts. No functionality was removed, and the reduction has no impact on the safety or effectiveness of the devices.

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.
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009



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- IEC62359, Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- 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)

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).