DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 10, 2016

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

Re: K160078
Trade/Device Name: Vivid T8
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 12, 2016
Received: January 14, 2016

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 at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K160078

Device Name
Vivid T8

Indications for Use *(Describe)*

The Vivid T8 is a multipurpose cardiovascular ultrasound system designed for cardiac and shared service imaging. The system supports the following applications: Fetal/OB, Abdominal, Pediatric, Small Organ, Cardiac, Peripheral Vascular, Adult Cephalic, Neonatal Cephalic, Musculoskeletal Superficial/Conventional,Transcranial, Transrectal, Transvaginal and Transesophageal.

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)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 T8. Combinations identified "P" represents those previously cleared with another GE Ultrasound system. Combinations identified as "N" are new.

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 Diagnostic Ultrasound System

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Small Organ (specify)[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Cardiac[3]	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	**P**	
Peripheral Vascular	**P**	**P**	**P**	**N**	**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Transorbital											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Transrectal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	4

N = new indication; P = previously cleared by FDA K141067; P^1 = previously cleared by FDA K121063;
P^2 = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics.

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with 4C-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Pediatric	**P**[1]	**P**[1]	**P**[1]		**P**[1]		**P**[1]	**P**[1]	**P**[1]	**P**[1]	
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage	**P**[2]	**P**[2]			**P**[2]		**P**[2]	**P**[2]	**P**[2]	**P**[2]	4

N = new indication; P = previously cleared by FDA K141067; P[1]= previously cleared by FDA K121063;

P[2] = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Vivid T8 with 8C-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]											
Pediatric	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Small Organ (specify)[2]											
Neonatal Cephalic	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage											

N = new indication; P = previously cleared by FDA K141067; P^1= previously cleared by FDA K121063;
P^2 = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with E8C-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Transvaginal	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage	**P^2**	**P^2**	**P^2**		**P^2**			**P^2**	**P^2**	**P^2**	4

N = new indication; P = previously cleared by FDA K141067; P^1= previously cleared by FDA K121063;
P^2 = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with 3Sc-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage	**P**[2]	**P**[2]	**P**[2]		**P**[2]	**P**[2]	**P**[2]	**P**[2]	**P**[2]	**P**[2]	4

N = new indication; P = previously cleared by FDA K141067; P[1] = previously cleared by FDA K121063;
P[2] = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with 6S-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Small Organ (specify)[2]											
Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage											

N = new indication; P = previously cleared by FDA K141067; P^1= previously cleared by FDA K121063;
P^2 = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with 12S-RS Transducer

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

Clinical Application / *Anatomy/Region of Interest*	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
			PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**N**	
Pediatric	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**		**P[1]**	**P[1]**	**N**	
Small Organ (specify)[2]											
Neonatal Cephalic	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**N**	
Adult Cephalic											
Cardiac[3]	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**		**P[1]**	**P[1]**	**N**	
Peripheral Vascular	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**N**	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage											

N = new indication; P = previously cleared by FDA K141067; P[1]= previously cleared by FDA K121063;
P[2] = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with 6Tc-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**	**P**	
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage											

N = new indication; P = previously cleared by FDA K141067; P^1= previously cleared by FDA K121063;
P^2 = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with P2D Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]				**P**							
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidanceof											
Tissue Biopsy / Fluid Drainage											

N = new indication; P = previously cleared by FDA K141067; P^1= previously cleared by FDA K121063;

P^2 = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

(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 Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with L6-12-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Small Organ (specify)[2]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Neonatal Cephalic	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage	**P**^{2}		**P**^{2}		**P**^{2}		**P**^{2}	**P**^{2}	**P**^{2}	**P**^{2}	4

N = new indication; P = previously cleared by FDA K141067; P^1= previously cleared by FDA K121063;
P^2 = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with 9L-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Pediatric	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Small Organ (specify)[2]	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Neonatal Cephalic	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Musculo-skeletal Conventional	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Musculo-skeletal Superficial	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidanceof											
Tissue Biopsy / Fluid Drainage	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	4

N = new indication; P = previously cleared by FDA K141067; P[1]= previously cleared by FDA K121063;
P[2] = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid T8 with 12L-RS Transducer

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse**	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Pediatric	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Small Organ (specify)[2]	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Neonatal Cephalic	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Musculo-skeletal Conventional	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Musculo-skeletal Superficial	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidanceof											
Tissue Biopsy / Fluid Drainage	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	4

N = new indication; P = previously cleared by FDA K141067; P[1]= previously cleared by FDA K121063;
P[2] = previously cleared by FDA K133034

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement;
[*] Combined modes are B/M, B/PWD, B/Color/PWD
[**] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

510(k) Summary

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

Date:	January 12, 2016
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 F:(414)918-8275
Secondary Contact Person:	Nick Xu Regulatory Affairs GE Medical Systems (China) Co, Ltd. T: +86 510 8527 8639 F: +86 510 8522 7347
Device: Trade Name:	Vivid T8
Common/Usual Name:	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
Predicate Device(s):	K141067 GE Vivid T8 / Vivid T8 Pro K121063 GE Vivid S5 / Vivid S6 K133034 GE LOGIQ F Series
Device Description:	The Vivid T8 is the full featured cardiovascular diagnostic ultrasound system designed for cardiac and shared service imaging which consists of a mobile console that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, color LCD image display and touch panel
Intended Use:	The Vivid T8 is a multipurpose cardiovascular ultrasound system intended for diagnostic ultrasound imaging and fluid flow analysis. The system supports the following applications: Fetal/OB, Abdominal, Pediatric, Small Organ, Cardiac, Peripheral Vascular, Adult Cephalic, Neonatal Cephalic,

Musculoskeletal Superficial/ Conventional, Transcranial, Transrectal, Transvaginal and Transesophageal.

Technology: The Vivid T8 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The Vivid T8 system is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The Vivid T8 and predicate Vivid T8 (K141067 systems have the same clinical indications. The IFU tables are being updated to clarify biopsy/needle guidance on the 4C-RS, E8C-RS, L6-12-RS and 3Sc-RS which was cleared per predicate LOGIQ F (K133034) and is added with 9L-RS and 12L-RS that are added with this submission.
- The Vivid T8 and predicate Vivid T8 systems have the same imaging modes.
- The Vivid T8 and predicate Vivid T8 systems transducers are identical except for the 12S-RS, 9L-RS and 12L-RS which are the same transducers cleared in predicate Vivid S5/S6 (K121063).
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The Vivid T8 and predicate Vivid T8 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The Vivid T8 and predicate Vivid T8 systems have been designed in compliance with approved electrical and physical safety standards.
- The Scan Coach feature is being added and is equivalent to that cleared in the LOGIQ F Series (K133034).
- Smart Start feature with battery is being added and is equivalent to that cleared in Vivid S5/S6 (K121063).
- The embedded operating system has been changed from Window XP to Windows 7.

- An update has been made to the hardware flex arm.

Summary of Non-Clinical Tests:

Vivid T8 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 T8 complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing- Third Edition
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- ISO14971, Application of risk management to medical devices
- NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

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

- Risk 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)

Transducer material and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Vivid T8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid T8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).