November 6, 2018

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

Re: K181934
Trade/Device Name: Vivid T8, Vivid T9
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 1, 2018
Received: November 2, 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181934

Device Name
Vivid T8, Vivid T9

Indications for Use *(Describe)*

The Vivid T9 / Vivid T8 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Fetal/OB, Abdominal, Pediatric, Small Organ, Cardiac, Peripheral Vascular, Adult Cephalic, Neonatal Cephalic, Musculoskeletal Superficial/Conventional, Transcranial, Transrectal, Transvaginal, Transesophageal, Intraoperative and Tissue Biopsy.

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 T8 and Vivid T9. 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 T8, Vivid T9
Transducer: 4C-RS
Transducer: 8C-RS
Transducer: E8C-RS
Transducer: 3Sc-RS
Transducer: 6S-RS
Transducer: 12S-RS
Transducer: 6Tc-RS
Transducer: P2D
Transducer: L6-12-RS
Transducer: 9L-RS
Transducer: 12L-RS
Transducer: 9T-RS
Transducer: L8-18i-RS
Transducer: C1-5-RS (Only for Vivid T9)
Transducer: E8Cs-RS (Only for Vivid T9)

GE Vivid T8 / Vivid T9 Ultrasound System

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics	**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 [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**	
Peripheral Vascular	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Other											
Exam Type, Means of Access											
Transcranial	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
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 [4]	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	**P**				**P**		**P**		**P**		

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 4C-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Abdominal [1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	**P**[1]	**P**[1]	**P**[1]		**P**[1]	**N**	**P**[1]	**P**[1]	**P**[1]	**P**[1]	
Musculo-skeletal Superficial	**P**[1]	**P**[1]	**P**[1]		**P**[1]	**N**	**P**[1]	**P**[1]	**P**[1]	**P**[1]	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	**P**				**P**		**P**		**P**		

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 8C-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P		P	P[2]	P	P	P	P	
Pediatric	P	P	P		P	P[2]	P	P	P	P	
Small Organ [2]	P[1]	P[1]	P[1]		P[1]	N	P[1]	P[1]	P[1]	P[1]	
Neonatal Cephalic	P	P	P		P	P[2]	P	P	P	P	
Adult Cephalic											
Cardiac[3]	P[1]	P[1]	P[1]		P[1]	P[2]	P[1]	P[1]	P[1]	P[1]	
Peripheral Vascular	P	P	P		P	P[2]	P	P	P	P	
Musculo-skeletal Conventional	P[1]	P[1]	P[1]		P[1]	N	P[1]	P[1]	P[1]	P[1]	
Musculo-skeletal Superficial	P[1]	P[1]	P[1]		P[1]	N	P[1]	P[1]	P[1]	P[1]	
Other											
Exam Type, Means of Access											
Transcranial	P[3]	P[3]	P[3]		P[3]	P[3]	P[3]	P[3]	P[3]	P[3]	
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]											

N= new indication; P= previously cleared by FDA K160078; P[1] = previously cleared by FDA K151028. P[2]= previously cleared by FDA K161706. P[3]= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with E8C-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**	**P**[3]	**P**	**P**	**P**	**P**	
Abdominal [1]	**P**	**P**	**P**		**P**	**P**[3]	**P**	**P**	**P**	**P**	
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**	**P**[3]	**P**	**P**	**P**	**P**	
Transvaginal	**P**	**P**	**P**		**P**	**P**[3]	**P**	**P**	**P**	**P**	
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	**P**				**P**		**P**[1]		**P**		

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 3Sc-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]		
Abdominal [1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P		P	P		
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac[3]	P	P	P	P	P	P		P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial	P	P	P	P	P	P	P	P	P		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	P				P				P		

N= new indication; P= previously cleared by FDA K160078; P[1] = previously cleared by FDA K151028. P[2]= previously cleared by FDA K161706. P[3]= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 6S-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P		P	P		
Abdominal [1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P[2]	P	P		
Small Organ [2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P		P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]											

N= new indication; P= previously cleared by FDA K160078; P[1] = previously cleared by FDA K151028. P[2]= previously cleared by FDA K161706. P[3]= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 12S-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P[2]	P	P		
Small Organ [2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P		P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]											

N= new indication; P= previously cleared by FDA K160078; P[1] = previously cleared by FDA K151028. P[2]= previously cleared by FDA K161706. P[3]= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 6Tc-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]											

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with P2D Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]				**P**							
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]											

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with L6-12-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Small Organ [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**	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	**P**				**P**		**P**		**P**		

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

Notes: [1] Abdominal includes GYN and Urological;
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[4] Intraoperative includes abdominal, thoracic and peripheral;
[5] Includes image guidance for freehand needle placement;
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid T8 / Vivid T9 with 9L-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Small Organ [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**	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	**P**				**P**		**P**		**P**		

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 12L Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [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	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	P				P		P		P		

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596.

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

GE Vivid T8 / Vivid T9 with 9T-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	E	E	E	E	E	E		E	E	E	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal	E	E	E	E	E	E		E	E	E	
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]											

N= new indication; P= previously cleared by FDA K160078; P[1] = previously cleared by FDA K151028. P2= previously cleared by FDA K161706. P3= previously cleared by FDA K163596. E = added under Appendix E per K16706.

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

GE Vivid T8 / Vivid T9 with L8-18i Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric											
Small Organ [2]	E	E	E		E	E	E	E	E	E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	E	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]	P^2	P^2	P^2		P^2	P^2	P^2	P^2	P^2	P^2	
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]											

N= new indication; P= previously cleared by FDA K160078; P^1 = previously cleared by FDA K151028. P^2= previously cleared by FDA K161706. P^3= previously cleared by FDA K163596. E = added under Appendix E per K16706.

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

GE Vivid T9 with C1-5-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	
Abdominal [1]	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	
Pediatric	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P[2]	P[2]	P[2]		P[2]	N	P[2]	P[2]	P[2]	P[2]	
Musculo-skeletal Superficial	P[2]	P[2]	P[2]		P[2]	N	P[2]	P[2]	P[2]	P[2]	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	P[2]				P[2]		P[2]		P[2]		

N= new indication; P= previously cleared by FDA K160078; P[1] = previously cleared by FDA K151028. P[2]= previously cleared by FDA K161706. P[3]= previously cleared by FDA K163596.

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

GE Vivid T9 with E8Cs-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes[*]	Harmonic Imaging	Coded Pulse[**]	Other
Ophthalmic											
Fetal / Obstetrics	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	
Abdominal [1]	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	
Transvaginal	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[2]	P[2]	P[2]	
Intraoperative [4]											
Interventional Guidance											
Tissue Biopsy / Fluid Drainage[5]	P[2]				P[2]		P[2]		P[2]		

N= new indication; P= previously cleared by FDA K160078; P[1] = previously cleared by FDA K151028. P[2]= previously cleared by FDA K161706. P[3]= previously cleared by FDA K163596.

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

510(k) Summary

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

Date:	July 17, 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 tracey.ortiz@ge.com
Secondary Contact Person:	Yu Wen Regulatory Affairs GE Healthcare
Device Trade Name:	Vivid T8, Vivid T9
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 T8 (K160078)
Secondary Predicate Device(s):	Vivid E95(K170823) Vivid iq (K161706) Vscan Extend (K180995) Additional predicates used for changes to transducer applications: LOGIQ e (K151028), LOGIQ P9 and LOGIQ P7 (K163596).
Device Description:	The Vivid T9 / Vivid T8 is a high performance digital ultrasound imaging system with total data management. The system provides image generation in 2D (B) Mode, Color Doppler, Power Doppler (Angio), M-Mode, Color M-Mode, PW and CW Doppler spectral, Tissue Velocity imaging, advanced Strain and Contrast applications. The fully digital architecture of the Vivid T9 / Vivid T8 unit allows optimal usage of all scanning modes and probe types, throughout the full spectrum of operating frequencies.

Intended Use: The Vivid T9 / Vivid T8 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Fetal/OB, Abdominal, Pediatric, Small Organ, Cardiac, Peripheral Vascular, Adult Cephalic, Neonatal Cephalic, Musculoskeletal Superficial/Conventional, Transcranial, Transrectal, Transvaginal, Transesophageal, Intraoperative and Tissue Biopsy.

Technology: The Vivid T8 / Vivid T9 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The Vivid T8 / Vivid T9 system is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for ultrasound imaging, measurement and analysis of the human body and fluid for multiple clinical applications.
- The Vivid T8, Vivid T9 and predicate Vivid T8 (K160078) have similar clinical indications for use, however the proposed Vivid T8 / Vivid T9 has the Intraoperative indication which has been cleared on predicate Vivid iq (K161706).
- The Vivid T8, Vivid T9 and predicate Vivid T8 have identical imaging modes.
- The Vivid T8, Vivid T9 and predicate Vivid T8 (K160078) transducers are similar, except for adding C1-5-RS and E8Cs-RS on Vivid T9 which were cleared with predicate Vivid iq (K161706). The 9T-RS and the L8-18i-RS transducers were previously added though appendix E of the ultrasound guidance. However intraoperative is now being added to the L8-18i-RS transducer per predicate Vivid iq (K161706).
- The Vivid T8 / Vivid T9 is adding clinical applications to the 4C-RS, 8C-RS, 3Sc-RS,6S-RS, 12S-RS, 9T-RS, L8-18i-RS, C1-5-RS and E8Cs-RS transducers that were cleared on prior systems.
- The Vivid T8 / Vivid T9 is adding new features called Virtual convex, QuickApps, Cardiac AutoDoppler, Virtual Apex, Strain and Strain Rate, which were all cleared in predicate Vivid E95 (K170823).

- The Vivid T8 / Vivid T9 is adding a new feature called Tricefy Uplink, which was cleared with predicate Vscan Extend (K180995).
- AFI and Auto EF which were cleared on predicate Vivid T8 (K160078) have improvements made to them.
- Adding Pediatric Z-score based on Z-Scores cleared in the predicate Vivid E95(K170823) includes expanded data.
- The Vivid T8, Vivid T9 and predicate Vivid T8 (K160078) have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- 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, Vivid T9 and predicate Vivid T8 (K160078) have been designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests:

Vivid T8 / Vivid T9 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 / Vivid T9 complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/ A2:2012
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2014
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009

- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, 2004
- 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 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)

Transducer material and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Vivid T8 / Vivid T9, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid T8 / Vivid T9 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).