December 6, 2018

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

Re: K181727
Trade/Device Name: Vivid iq
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 2, 2018
Received: November 5, 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 and Part 809); 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 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
K181727

Device Name
Vivid iq

Indications for Use *(Describe)*

The Vivid iq is a high-performance compact ultrasound system designed for cardiovascular and shared services applications. The indications of the product will include Fetal, OB, Abdominal, Pediatric, small Organ, Neonatal Cephalic, Adult Cephalic, Cardiac, Peripheral Vascular, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Transcranial, Transrectal, Transvaginal, Transesophageal, Tissue biopsy, Intraoperative, IntraCardiac and Intraluminal.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Vivid *iq*. 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 *iq*
Transducer: 3Sc-RS
Transducer: M5Sc-RS
Transducer: 6S-RS
Transducer: 12S-RS
Transducer: 6Tc-RS
Transducer: 6VT-D
Transducer: P2D
Transducer: 9T-RS
Transducer: AcuNav 10F (G version)
Transducer: AcuNav 8F (G version)
Transducer: SOUNDSTAR 3D 10F (G version)
Transducer: SOUNDSTAR eco 8F (G version)
Transducer: SOUNDSTAR eco 10F (G version)
Transducer: 9L-RS
Transducer: 12L-RS
Transducer: ML6-15-RS
Transducer: L8-18i-RS
Transducer: 4C-RS
Transducer: C1-5-RS
Transducer: E8Cs-RS
Transducer: 8C-RS

GE Vivid *iq* 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		
Cardiac[3]	P	P	P	P	P	P		P	P	P	6
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial	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	6
Transrectal	P	P	P		P	P	P	P	P	P	
Transvaginal	P	P	P		P	P	P	P	P	P	
Intraoperative [4]	P	P	P	P	P	P	P	P	P	P	
Interventional Guidance											
Intracardiac and Intraluminal	P	P	P	P	P	P		P	P		
Tissue Biopsy[5]	P				N		P		P		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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	P	P	P	P	P	P	P	P		
Abdominal [1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P		P	P		
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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	P				P[1]		P				
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with M5Sc-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**	**P**		
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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	**P**				**P**		**P**				
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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	P	P		
Small Organ [2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac[3]	P[1]	P[1]	P[1]	P[1]	P[1]	P[1]		P[1]	P[1]		
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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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	P	P		
Small Organ [2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac[3]	P^2	P^2	P^2	P^2	P^2	P^2		P^2	P^2		
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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with 6VT-D Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	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**		**6**
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		**6**
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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]	**P**	**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**	**P**	
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with AcuNav 10F (G version) 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]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Interventional Guidance											
Intracardiac and Intraluminal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with AcuNav 8F (G version) 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]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Interventional Guidance											
Intracardiac and Intraluminal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with SOUNDSTAR 3D 10F (G version) 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]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Interventional Guidance											
Intracardiac and Intraluminal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with SOUNDSTAR eco 8F (G version) 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]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Interventional Guidance											
Intracardiac and Intraluminal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with SOUNDSTAR eco 10F (G version) 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]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Interventional Guidance											
Intracardiac and Intraluminal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	P				P		P		P		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with 12L-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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	**P**				**P**		**P**		**P**		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with ML6-15-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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	**P**				**P**		**P**		**P**		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* with L8-18i-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]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Interventional Guidance											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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**	**P**	
Abdominal [1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
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]	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	**P**				**P**		**P**		**P**		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Abdominal [1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
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]	
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [4]											
Interventional Guidance											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	**P**				**P**		**P**		**P**		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Abdominal [1]	**P**	**P**	**P**		**P**	**P**	**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**	**P**	**P**	**P**	**P**	
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Intraoperative [4]											
Interventional Guidance											
Intracardiac and Intraluminal											
Tissue Biopsy[5]	**P**				**P**		**P**		**P**		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P^1= previously cleared by FDA K151028. P^2= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

GE Vivid *iq* 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	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ [2]	P[1]	P[1]	P[1]		P[1]		P[1]	P[1]	P[1]	P[1]	
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac[3]	P	P	P		P	P	P	P	P	P	
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
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]	
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											
Intracardiac and Intraluminal											
Tissue Biopsy[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K161706; P[1]= previously cleared by FDA K151028. P[2]= previously cleared by FDA K160078. 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 thoracic(cardiac) and vascular (PV);
[5] Includes image guidance for freehand needle placement
[6] RT 3D Mode
[*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[**] Coded Pulse is for digitally encoded harmonics.

510(k) Summary
K181727

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

Date:	June 28, 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 Email:tracey.ortiz@ge.com
Secondary Contact Person:	Yu Wen Regulatory Affairs GE Healthcare GE Medical Systems China Co., LTD
Device Trade Name:	Vivid *iq*
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 *iq* (K161706)
Secondary Predicate Device(s):	Vivid E95(K170823) Venue (K180599) Vscan Extend (K161588) Predicates used for changes to transducer applications: LOGIQ e(K151028), Vivid T8 (K160078), LOGIQ P9 and LOGIQ P7 (K163596).
Device Description:	The Vivid *iq* is a high-performance compact ultrasound system designed for cardiovascular and shared services applications. It offers an innovative ergonomic design, superb image quality, advanced connectivity, productivity tools and advanced technology. Compatibility with the Vivid product family offers flexibility in lab configuration and upgrade opportunities.

New technology added:	4D Markers function to Vivid iq allow the user to manually place annotations/markers into 3D/4D ultrasound datasets. The purpose is to aid communication between medical personnel, especially to a person not familiar with ultrasound. The Tricefy™ Uplink to Vivid iq Apps which includes the interface to Tricefy. Tricefy is a cloud-based solution to support archiving, collaboration and exchange of images, clips and reports. Tricefy and Tricefy Uplink are products of Trice Imaging. Qview feature provides a communication pathway with Qpath: Qview is the name of a component provided by the vendor of the popular product Qpath. To access the reporting capability of Qpath product from the ultrasound scanner the user opens the Qview feature. Qpath and Qview are products of Telexy Healthcare. QuickApps will allow the user to maintain the current scanning mode and image geometry parameters, such as 2D Depth, 2D Width, Color ROI size and position, as already adjusted by the user, while optimizing other imaging parameters according to a selected scanning situation at any given time. View-X functionality is to view a live video stream from another imaging modality at the same time of live ultrasound imaging for informational use when both modalities are used as imaging-support for interventional procedures. FlexiViews allow the user quick access to standard user-defined views when scanning with 4D TEE transducers. FlexiViews will store image geometry and a set of scanning parameters.
Intended Use:	The Vivid iq is a high-performance compact ultrasound system designed for cardiovascular and shared services applications. The indications of the product will include Fetal, OB, Abdominal, Pediatric, small Organ, Neonatal Cephalic, Adult Cephalic, Cardiac, Peripheral Vascular, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Transcranial, Transrectal, Transvaginal, Transesophageal, Tissue biopsy, Intraoperative, IntraCardiac and Intraluminal.

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

Determination of Substantial Equivalence: Comparison to Predicate Devices

The Vivid *iq* 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 *iq* and predicate Vivid *iq* (K161706) have same clinical indications for use.
- The Vivid *iq* and predicate Vivid *iq* (K161706) have identical imaging modes.
- The Vivid *iq* and predicate Vivid *iq* (K161706) systems transducers are the same.
- Adding clinical applications to the 6S-RS,12S-RS, 4C-RS, C1-5-RS and 8C-RS transducers based on clearances from LOGIQ e (K151028), Vivid T8 (K160078) and LOGIQ P9 and LOGIQ P7 (K163596).
- Adding new features called FlexiViews, Virtual convex, QuickApps, View-X, Mitral Valve Quantification (MVQ), 4D AVQ. All cleared in predicate Vivid E95(K160078).
- Adding new feature called Tricefy Uplink, which was cleared in predicate Vscan Extend (K161588).
- Adding new feature called Qview, which was cleared in predicate Venue (K180599).
- AFI, Auto EF and Cardiac AutoDoppler features cleared on predicate Vivid *iq* (K161706) have improvements.
- Adding Pediatric Z-score based on Z-Scores in the predicate Vivid E95(K170823) with expanded data.
- The Vivid *iq* and predicate Vivid *iq* (K161706) have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The system is 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 *iq* and predicate Vivid *iq* (K161706) have been designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests:

Vivid *iq* 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 *iq* 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 proposed Vivid iq Ultrasound System also complies with the FDA ultrasound specific guidance, Guidance for Industry and FDA Staff – Information for manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008).

Non-Clinical verification testing has been performed to cover system level requirements and the risk control measures. Non-Clinical validation testing covered the intended use and commercial claims as well as usability testing with representative intended users.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the proposed Vivid iq Ultrasound Systems comply with international and FDA-recognized consensus standards and FDA ultrasound guidance document and meet the acceptance criteria and are adequate for their intended use.

Therefore, the proposed Vivid iq Diagnostic Ultrasound Systems are substantially equivalent to the predicate in terms of safety and effectiveness.

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 *iq*, did not require clinical studies to support substantial equivalence.

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