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

May 2, 2018

Re: K180599
Trade/Device Name: Venue
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: March 7, 2018
Received: March 8, 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. 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.

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.

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

Sincerely,

Michael D. O'Hara 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 *(if known)*

K180599

Device Name
Venue

Indications for Use *(Describe)*

The Venue is a general purpose diagnostic ultrasound system for use by qualified healthcare professionals. The clinical environments where the Venue can be used include critical care and emergency room environments, as well as point-of care areas in offices, clinical and hospital settings for diagnosis of patients.
The Venue is intended for ultrasound imaging, measurement and analysis of the human body and fluid for multiple clinical applications including: abdominal (GYN and Urology), thoracic/pleural, ophthalmic, Fetal/OB, Small Organ (including breast, testes, thyroid), Peripheral vascular, neonatal and adult cephalic, pediatric, musculoskeletal (conventional and superficial), cardiac (adults and pediatric), Transrectal, Transvaginal, Transesophageal, and imaging guidance of interventional procedures (e.g. Nerve block, vascular access).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Venue. 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: Venue
Transducer: 3Sc-RS
Transducer: 9L-RS
Transducer: C1-5-RS
Transducer: 8C-RS
Transducer: E8C-RS
Transducer: 12L-RS
Transducer: L12n-RS
Transducer: 6Tc-RS

GE Venue 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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic	P				P		P				
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]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic	P	P	P		P	P	P	P	P	P	
Pediatric Cardiac	P	P	P	P	P	P	P^2	P	P	P^2	6
Adult Cardiac	P	P	P	P	P	P	P^2	P	P	P^2	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	
Thoracic/Pleural [3]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal	P^2	P^2	P^2	P^2	P^2	P^2		N	P^2	P^2	6
Transrectal	P	P	P		P	P	P	P	P	P	
Transvaginal	P	P	P		P	P	P	P	P	P	
Interventional Guidance											
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	5,7
Nonvascular [5]	P	P	P		P	P	P	P	P	P	5,7

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics;

GE Venue 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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse ♦	Other
Ophthalmic	P				P		P				
Fetal / Obstetrics	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 [2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P		P	P	P	P	P		
Pediatric Cardiac	P	P	P	P	P	P		P	P		6
Adult Cardiac	P	P	P	P	P	P		P	P		6
Peripheral Vascular	P	P	P		P	P	P	P	P		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural [3]	P	P	P		P	P	P	P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Interventional Guidance											
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P		7
Nonvascular [5]											

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics;

GE Venue 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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse ♦	Other
Ophthalmic	**N**				**N**		**N**				
Fetal / Obstetrics	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
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**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Neonatal Cephalic	**P^2**	**P^2**	**P^2**		**P^2**	**N**	**P^2**	**N**	**P^2**	**P^2**	
Adult Cephalic											
Pediatric Cardiac	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Adult Cardiac	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
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**	
Thoracic/Pleural [3]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**
Nonvascular [5]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.

GE Venue 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 Doppler	Power Doppler	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											
Pediatric Cardiac	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Adult Cardiac	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
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**	
Thoracic/Pleural [3]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**7**
Nonvascular [5]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**7**

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.

GE Venue 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 Doppler	Power Doppler	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	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric Cardiac	**P²**	**P²**	**P²**		**P²**	**P²**	**P²**	**N**	**P²**	**P²**	
Adult Cardiac	**P²**	**P²**	**P²**		**P²**	**P²**	**P²**	**N**	**P²**	**P²**	
Peripheral Vascular	**P²**	**P²**	**P²**		**P²**	**P²**	**P²**	**N**	**P²**	**P²**	
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 [3]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [5]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.

GE Venue 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 Doppler	Power Doppler	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											
Pediatric Cardiac											
Adult Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural [3]											
Exam Type, Means of Access											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [5]											

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
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[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.

GE Venue 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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse ♦	Other
Ophthalmic	P				P		P				
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	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P^2	P^2	P^2		P^2	N	P^2	P^2	P^2	P^2	
Adult Cephalic											
Pediatric Cardiac	N	N	N		N	N	N	N	N	N	
Adult Cardiac	N	N	N		N	N	N	N	N	N	
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	
Thoracic/Pleural [3]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Interventional Guidance											
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	5,7
Nonvascular [5]	P	P	P		P	P	P	P	P	P	5,7

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.

GE Venue with L12n-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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic	**P**				**P**		**P**				
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**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Neonatal Cephalic	**P^1**	**P^1**	**N**		**P^1**	**N**	**P^1**	**P^1**	**P^1**	**N**	
Adult Cephalic											
Pediatric Cardiac	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Adult Cardiac	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
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**	
Thoracic/Pleural [3]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**
Nonvascular [5]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.

GE Venue 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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Pediatric Cardiac											
Adult Cardiac	**P²**	**P²**	**P²**	**P²**	**P²**	**P²**		**N**	**P²**	**P²**	**6**
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural [3]											
Exam Type, Means of Access											
Transesophageal	**P²**	**P²**	**P²**	**P²**	**P²**	**P²**		**N**	**P²**	**P²**	**6**
Transrectal											
Transvaginal											
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [5]											

N = new indication; P = previously cleared by FDA K170714; P^1 = previously cleared by FDA K163596; P^2 = previously cleared by FDA K161706;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Including detection of fluid and pleural motion/sliding;
[4] Nonvascular includes nerve block or biopsy;
[5] Biopsy bracket available;
[6] Combined modes as defined in [*], but exclude B/Power/PWD, and include: B/CWD, B/Color/CWD;
[7] Image guidance supports freehand needle/catheter placement;
[*] Combined modes are: B/M, B/Color 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:	March 6, 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)470-1003 F:(414)918-8275
Secondary Contact Person:	Karin Shimoni Regulatory Affairs Leader GE Healthcare
Device Trade Name:	Venue
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:	Venue (K170714)
Secondary Predicate Device(s):	LOGIQ e (K151028) Vivid iq (K161706) LOGIQ P9 and LOGIQ P7 (K163596)
Device Description:	The proposed Venue system is a general-purpose, Track 3, diagnostic ultrasound device, intended for ultrasound imaging, measurement and analysis of the human body and fluid that provides digital acquisition, processing and display capabilities. Venue can be used in offices, clinical areas and hospitals. The Venue is a mobile system with a small footprint that easily fits into tight spaces and positioned to accommodate the sometimes-awkward work settings of the point of care user. The Venue has a high resolution color LCD monitor, with a simple, multi-touch user interface that makes the system intuitive. The single surface screen can be cleaned with disinfectants. Articulated monitor arm enables flexible display positions in

order to be accessible and clearly visible in both user-standing and sitting positions.
The proposed Venue has the capability for displaying the patient's ECG trace synchronized to the scanned image. This allows the user to view an image from a specific time of the ECG signal. The ECG signal can be input directly from the patient or as an output from an ECG monitoring device. ECG is not intended for monitoring or diagnosis.
The Venue has a battery that allows for scanning without the need to plug in to an electrical outlet. The system is capable of wireless communication and a barcode reader is available to be used as an input device. System meets DICOM requirements to support users image storage and archiving needs and allows for output to printing devices. The user documentation is available via electronic media.
The Venue utilizes a variety of linear, convex, and phased array transducers which provide high imaging capability, supporting all standard acquisition modes. Some biopsy kits are available for needle-guidance procedures. The system includes several automated tools designed to simplify and shorten the workflow time of the healthcare professional for some common assessments.

Intended Use: The Venue is a general purpose diagnostic ultrasound system for use by qualified healthcare professionals. The clinical environments where the Venue can be used include critical care and emergency room environments, as well as point-of care areas in offices, clinical and hospital settings for diagnosis of patients. The Venue is intended for ultrasound imaging, measurement and analysis of the human body and fluid for multiple clinical applications including: abdominal (GYN and Urology), thoracic/pleural, ophthalmic, Fetal/OB, Small Organ (including breast, testes, thyroid), Peripheral vascular, neonatal and adult cephalic, pediatric, musculoskeletal (conventional and superficial), cardiac (adults and pediatric), Transrectal, Transvaginal, Transesophageal, and imaging guidance of interventional procedures (e.g. Nerve block, vascular access).

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

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The Venue 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 Venue and predicate Venue (K170714) have similar clinical indications for use however the proposed Venue has the Transesophageal indication which has been cleared on predicate Vivid iq (K161706). Proposed Venue has removed Pinpoint™ GT Technology SW.
- The Venue and predicate Venue (K170714) have identical imaging modes.
- The Venue and predicate Venue (K170714) systems transducers are similar, except for adding 6Tc-RS, cleared in Vivid iq (K161706), and adding clinical applications to the 9L-RS, C1-5-RS, 8C-RS, 12L-RS and L12n-RS probes.
- Automated features cleared on predicate Venue (K170714) have improvements, to assist the user workflow.
- Addition of the ECG module for ECG trace/image synchronization that was cleared with predicate LOGIQ e (K151028).
- Adding eFAST Navigation Tool and Review Summary feature that automates the workflow for the eFAST exam that can be done manually.
- The Venue and predicate Venue (K170714) 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 Venue and predicate Venue (K170714) have been designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests:

Venue 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 Venue 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, 2007
- 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, Venue, did not require clinical studies to support substantial equivalence.

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