January 28, 2019

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

Re: K183362
Trade/Device Name: Venue Go
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 3, 2018
Received: December 4, 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 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)*
K183362

Device Name
Venue Go

Indications for Use *(Describe)*
Venue Go is a general-purpose diagnostic ultrasound system intended for use by qualified healthcare professionals for ultrasound imaging, measurement and analysis of the human body and fluid. Venue Go clinical applications include the following: Abdominal (including Gynecology and Urology), Thoracic/Pleural, Ophthalmic, Fetal/Obstetrics, Small Organ (including breast, testes, thyroid), Peripheral vascular, Adult and neonatal cephalic, Pediatric, Musculoskeletal (Conventional and Superficial), Cardiac (Adults and Pediatric), Transesophageal, Transrectal, Transvaginal, Intraoperative and Imaging guidance for interventional procedures (e.g. Nerve block, biopsy, 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.

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:

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"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 Venue Go. 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 Go
Transducer: 3Sc-RS
Transducer: 9L-RS
Transducer: C1-5-RS
Transducer: 8C-RS
Transducer: E8C-RS
Transducer: 12L-RS
Transducer: 6Tc-RS
Transducer: L4-12t-RS
Transducer: L8-18i-RS
Transducer: 6S-RS

GE Venue Go 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	**N**				**N**		**N**				
Fetal / Obstetrics	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Abdominal [1]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Pediatric	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Small Organ [2]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Neonatal Cephalic	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Adult Cephalic	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Pediatric Cardiac	**N**	**N**	**N**	**N**	**N**	**N**		**N**	**N**	**N**	**6,8**
Adult Cardiac	**N**	**N**	**N**	**N**	**N**	**N**		**N**	**N**	**N**	**6,8**
Peripheral Vascular	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Musculo-skeletal Conventional	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Musculo-skeletal Superficial	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Thoracic/Pleural [3]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Exam Type, Means of Access											
Transesophageal	**N**	**N**	**N**	**N**	**N**	**N**		**N**	**N**		**6**
Transrectal	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Transvaginal	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Intraoperative [9]	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	
Interventional Guidance											
Vascular Access (IV, PICC)	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**5,7**
Nonvascular [4]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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**	**P**	**P**		**P**	**P**	**P**	**P**	**P**		
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											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**		
Nonvascular [4]											

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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	**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											
Pediatric Cardiac	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
Adult Cardiac	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
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											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**
Nonvascular [4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
Adult Cardiac	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
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											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**7**
Nonvascular [4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**7**

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.
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GE Venue Go 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											
Pediatric Cardiac	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
Adult Cardiac	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
Peripheral Vascular	**P**	**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**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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**	
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [4]											

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
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[7] Image guidance supports freehand needle/catheter placement;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Pediatric Cardiac	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
Adult Cardiac	**P**	**P**	**P**		**P**	**P**		**P**	**P**	**P**	**8**
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											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**
Nonvascular [4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	**5,7**

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
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[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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		**6**
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural [3]											
Exam Type, Means of Access											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**		**P**	**P**		**6**
Transrectal											
Transvaginal											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [4]											

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go with L4-12t-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[2]				P[2]		P[2]				
Fetal / Obstetrics											
Abdominal [1]	N	N	N		N	N	N	N	N	N	
Pediatric	P[2]	P[2]	P[2]		P[2]	P[1]	P[2]	P[1]	P[2]	P[1]	
Small Organ [2]	P[2]	P[2]	P[2]		P[2]	P[1]	P[2]	P[1]	P[2]	P[1]	
Neonatal Cephalic											
Adult Cephalic											
Pediatric Cardiac	N	N	N		N	N		N	N	N	8
Adult Cardiac	N	N	N		N	N		N	N	N	8
Peripheral Vascular	P[2]	P[2]	P[2]		P[2]	P[1]	P[2]	P[1]	P[2]	P[1]	
Musculo-skeletal Conventional	P[2]	P[2]	P[2]		P[2]	P[1]	P[2]	P[1]	P[2]	P[1]	
Musculo-skeletal Superficial	P[2]	P[2]	P[2]		P[2]	P[1]	P[2]	P[1]	P[2]	P[1]	
Thoracic/Pleural [3]	P[2]	P[2]	P[2]		P[2]	N	P[2]	N	P[2]	N	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)	P[2]	P[2]	P[2]		P[2]	N	P[2]	N	P[2]	P[2]	5,7
Nonvascular [4]	P[2]	P[2]	P[2]		P[2]	N	P[2]	N	P[2]	P[2]	5,7

N = new indication; P = previously cleared by FDA K180599; P[1] = previously cleared by FDA K181783; P[2] = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse ♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P2	P2	P2		P2		P2	P1	P2	P2	
Pediatric	P2	P2	P2		P2		P2	P1	P2	P2	
Small Organ [2]	P2	P2	P2		P2		P2	P1	P2	P2	
Neonatal Cephalic	P1	P1	P1		P1		P1	P1	P1	P1	
Adult Cephalic											
Pediatric Cardiac											
Adult Cardiac											
Peripheral Vascular	P2	P2	P2		P2		P2	P1	P2	P2	
Musculo-skeletal Conventional	P2	P2	P2		P2		P2	P1	P2	P2	
Musculo-skeletal Superficial	P2	P2	P2		P2		P2	P1	P2	P2	
Thoracic/Pleural [3]	P2	P2	P2		P2		P2	N	P2	P2	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [9]	P2	P2	P2		P2		P2	P1	P2	P2	
Interventional Guidance											
Vascular Access (IV, PICC)	P2	P2	P2		P2		P2	P1	P2	P2	7
Nonvascular [4]	P2	P2	P2		P2		P2	P1	P2	P2	7

N = new indication; P = previously cleared by FDA K180599; P^1 = previously cleared by FDA K181783; P^2 = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] 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 Go 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 Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse ♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	N	P[2]		
Pediatric	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[1]	P[2]		
Small Organ [2]											
Neonatal Cephalic	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	P[1]	P[2]		
Adult Cephalic											
Pediatric Cardiac	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]		P[1]	P[2]		6
Adult Cardiac	P[2]	P[2]	P[2]	P[2]	P[2]	P[2]		P[1]	P[2]		6
Peripheral Vascular	N	N	N		N	N	N	N	N		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural [3]	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	N	P[2]		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative [9]											
Interventional Guidance											
Vascular Access (IV, PICC)	P[2]	P[2]	P[2]		P[2]	P[2]	P[2]	N	P[2]		7
Nonvascular [4]											

N = new indication; P = previously cleared by FDA K180599; P[1] = previously cleared by FDA K181783; P[2] = previously cleared by FDA K151028;

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;
[8] Combined modes as defined in [*], but exclude B/Power/PWD;
[9] Intraoperative includes vascular;
[*] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[♦] Coded pulse is for digitally encoded harmonics.

K183362

510(k) Summary

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

Date:	December 3, 2018
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)676-6120
Secondary Contact Person:	Karin Shimoni Regulatory Affairs Leader GE Healthcare
Device Trade Name:	Venue Go
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 (K180599)
Secondary Predicate Device(s):	LOGIQ e (K151028) LOGIQ P9 (K181783)
Device Description:	Venue Go is a general-purpose diagnostic ultrasound system intended for use by qualified healthcare professionals to evaluate the body by ultrasound imaging and fluid flow analysis. The Venue Go is a compact, portable system with a small footprint. The system can be hand carried using an integrated handle, placed on a horizontal surface, attached to a mobile cart or wall mounted. It has a high resolution color LCD monitor, with a simple, multi-touch user interface that makes the system intuitive. The system can be powered through an electrical wall outlet for long term use or from an internal battery for a short time. The Venue Go utilizes a variety of linear, convex, and phased array transducers which provide high imaging performance and

support standard acquisition modes. Some biopsy kits are available for needle-guidance procedures.
The system 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 information is not intended for monitoring or diagnosis.
A barcode reader is available to be used as an input device.
Venue Go is capable of wireless communication through a built-in Wireless LAN device. The system meets DICOM requirements to support users image storage and archiving needs (local PACS or products such as Q-Path) and allows for output to printing devices. The user documentation is available electronically.
An additional accessory that will also be available for the customer will be a roller bag.

Intended Use: Venue Go is a general-purpose diagnostic ultrasound system intended for use by qualified healthcare professionals for ultrasound imaging, measurement and analysis of the human body and fluid. Venue Go clinical applications include the following: Abdominal (including Gynecology and Urology), Thoracic/Pleural, Ophthalmic, Fetal/Obstetrics, Small Organ (including breast, testes, thyroid), Peripheral vascular, Adult and neonatal cephalic, Pediatric, Musculoskeletal (Conventional and Superficial), Cardiac (Adults and Pediatric), Transesophageal, Transrectal, Transvaginal, Intraoperative and Imaging guidance for interventional procedures (e.g. Nerve block, biopsy, vascular access).

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

Determination of Substantial Equivalence: Comparison to Predicate Devices
The Venue Go 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 Go and predicate Venue (K180599) have similar clinical indications for use however the proposed

Venue Go has the Intraoperative indication which has been cleared on predicate LOGIQ e (K151028). Biopsy is being added and was incorporated in IFU tables of predicate Venue (K180599).

- The Venue Go and predicate Venue (K180599) have identical imaging modes.
- The Venue Go and predicate Venue (K180599) systems transducers are similar, except for addition of L4-12t-RS, L8-18i-RS and 6S-RS, which were cleared in LOGIQ e (K151028).
- The Venue Go is adding the Neonatal Cephalic application to L8-18i-RS, cleared in LOGIQ P9 (K181783). New applications of Abdominal & Cardiac (Pediatric and Adult) are added to the L4-12t-RS transducer, and Peripheral Vascular is added to the 6S-RS transducer.
- Venue Go is adding imaging modes of "Color M Doppler", "Combined Modes" (B/Color M) & "Coded Pulse" to L4-12t-RS, and "Combined Modes" (B/Color M) to 6S-RS & L8-18i-RS, all cleared in LOGIQ P9 (K181783).
- New Imaging modes are added to some applications:
  - "Combined mode" (B/Color M) added to Thoracic/Pleural, Vascular Access & Nonvascular on L4-12t-RS, Thoracic/Pleural on L8-18i-RS, and abdominal, Thoracic/Pleural & Vascular Access on 6S-RS.
  - "Color M Doppler" added to Thoracic/Pleural, Vascular Access & Nonvascular on L4-12t-RS.
  - "Coded pulse" added to Thoracic/Pleural on L4-12t-RS.
- The Venue Go and predicate Venue (K180599) 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 Go and predicate Venue (K180599) have been designed in compliance with approved electrical and physical safety standards.

- The Venue Go and predicate Venue (K180599) have identical SW features.

Summary of Non-Clinical Tests:

Venue Go 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 Go 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
- IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- ISO14971, Application of risk management to medical devices, 2007
- NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2016

The following quality assurance measures 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 Go, did not require clinical studies to support substantial equivalence.

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