DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 22, 2017

GE MEDICAL SYSTEMS ULTRASOUND
& PRIMARY CARE DIAGNOSTICS LLC
MS. TRACEY ORTIZ
REGULATORY AFFAIRS DIRECTOR
9900 W. INNOVATION DRIVE
WAUWATOSA, WI 53226

Re: K170714
Trade/Device Name: Venue
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, IYO
Dated: May 25, 2017
Received: May 26, 2017

Dear Ms. Ortiz:

This letter corrects our substantially equivalent letter of June 21, 2017.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

For

Robert Ochs
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K170714

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, and imaging guidance of interventional procedures (e.g. Nerve block, vascular access).

When Pinpoint GT Technology, from C.R. Bard, Inc., is included with the system, the Indications for Use include: Pinpoint GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.

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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"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. 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

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	**N**				**N**		**N**	**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**	
Cardiac [3]	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**		**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 [4]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Exam Type, Means of Access											
Transesophageal											
Transrectal	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Transvaginal	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**6,7,9**
Nonvascular [5]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**6,7,9**

N = new indication; P = previously cleared by FDA K151028; P^1 = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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**		**P**		
Fetal / Obstetrics	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**		
Abdominal [1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**		
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**		
Cardiac [3]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**		**8**
Peripheral Vascular	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural [4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**		**9**
Nonvascular [5]											

N = new indication; P = previously cleared by FDA K151028; P^1 = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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											
Fetal / Obstetrics											
Abdominal [1]	**P**	**P**	**P**		**P**	**P**[1]	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**	**P**[1]	**P**	**P**	**P**	**P**	
Small Organ [2]	**P**	**P**	**P**		**P**	**P**[1]	**P**	**P**	**P**	**P**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**[1]	**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	
Thoracic/Pleural [4]	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	**9**
Nonvascular [5]	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	**9**

N = new indication; P = previously cleared by FDA K151028; P^1 = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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[1]**	**P**	**P**	**P**	**P**	
Abdominal [1]	**P**	**P**	**P**		**P**	**P[1]**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**	**P[1]**	**P**	**P**	**P**	**P**	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	**P[1]**	**P[1]**	**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	
Thoracic/Pleural [4]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**9**
Nonvascular [5]	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	**9**

N = new indication; P = previously cleared by FDA K151028; P[1] = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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[1]**	**P**	**P**	**P**	**P[1]**	
Pediatric	**P**	**P**	**P**		**P**	**P[1]**	**P**	**P**	**P**	**P[1]**	
Small Organ [2]											
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P[1]**	**P**	**P**	**P**	**P[1]**	
Adult Cephalic	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**N**	
Cardiac [3]											
Peripheral Vascular											
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**N**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**N**	
Thoracic/Pleural [4]	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**N**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [5]											

N = new indication; P = previously cleared by FDA K151028; P[1] = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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**[1]	**P**	**P**	**P**	**P**[1]	
Abdominal [1]	**P**	**P**	**P**		**P**	**P**[1]	**P**	**P**	**P**	**P**[1]	
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural [4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**	**P**[1]	**P**	**P**	**P**	**P**[1]	
Transvaginal	**P**	**P**	**P**		**P**	**P**[1]	**P**	**P**	**P**	**P**[1]	
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)											
Nonvascular [5]											

N = new indication; P = previously cleared by FDA K151028; P[1] = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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**	**P**	**P**	**P**	
Fetal / Obstetrics											
Abdominal [1]	**P**	**P**	**P**		**P**	**P¹**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**	**P¹**	**P**	**P**	**P**	**P**	
Small Organ [2]	**P**	**P**	**P**		**P**	**P¹**	**P**	**P**	**P**	**P**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P¹**	**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P¹**	**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P¹**	**P**	**P**	**P**	**P**	
Thoracic/Pleural [4]	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	**7, 9**
Nonvascular [5]	**P**	**P**	**P**		**P**	**N**	**P**	**P**	**P**	**P**	**7, 9**

N = new indication; P = previously cleared by FDA K151028; P[1] = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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[1]**				**P[1]**		**P[1]**	**P[1]**	**P[1]**	**N**	
Fetal / Obstetrics											
Abdominal [1]	**P[1]**	**P[1]**	**N**		**P[1]**	**N**	**P[1]**	**P[1]**	**P[1]**	**N**	
Pediatric	**P[1]**	**P[1]**	**N**		**P[1]**	**N**	**P[1]**	**P[1]**	**P[1]**	**N**	
Small Organ [2]	**P[1]**	**P[1]**	**N**		**P[1]**	**N**	**P[1]**	**P[1]**	**P[1]**	**N**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	**P[1]**	**P[1]**	**N**		**P[1]**	**N**	**P[1]**	**P[1]**	**P[1]**	**N**	
Musculo-skeletal Conventional	**P[1]**	**P[1]**	**N**		**P[1]**	**N**	**P[1]**	**P[1]**	**P[1]**	**N**	
Musculo-skeletal Superficial	**P[1]**	**P[1]**	**N**		**P[1]**	**N**	**P[1]**	**P[1]**	**P[1]**	**N**	
Thoracic/Pleural [4]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Vascular Access (IV, PICC)	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**6, 9**
Nonvascular [5]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**6, 9**

N = new indication; P = previously cleared by FDA K151028; P[1] = previously cleared by FDA K163596;

Notes: [1] Abdominal includes GYN and Urology (includes prostate);
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Including detection of fluid and pleural motion/sliding;
[5] Nonvascular includes nerve block or biopsy;
[6] Needle guidance with Pinpoint™ GT needle technology;
[7] Biopsy bracket available;
[8] Combined modes also include: B/CWD, B/Color/CWD;
[9] 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 8, 2017
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)676-6120 F:(414)918-8275
Secondary Contact Person:	Karin Shimoni Regulatory Affairs Leader GE Medical Systems Israel LTD.
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 50 (K152758)
Secondary Predicate Device(s):	LOGIQ e (K151028) Vivid S60/S70 (K142323) 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, with a focus in critical care and emergency rooms settings. 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 19” 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 Venue has a battery that allows scanning continuously for hours without the need to plug in to an electrical outlet. The system is capable of wireless communication and a barcode reader is optionally 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 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 and Pinpoint GT option is also available.

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, and imaging guidance of interventional procedures (e.g. Nerve block, vascular access). When Pinpoint™ GT Technology, from C.R. Bard, Inc., is included with the system, the Indications for Use include: Pinpoint™ GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.

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 50 (K152758) have similar clinical indications for use. Proposed Venue has Transrectal indication which has been cleared on predicate LOGIQ e (K151028).
- The Venue and predicate LOGIQ e (K151028) have similar imaging modes. Venue has additional Combined Modes (B/Color M, B/CWD, B/Color/CWD).
- The Venue and predicate LOGIQ e (K151028) systems transducers are similar however there are new applications added to the 3Sc-RS and C1-5-RS probes. The Venue includes the L12n-RS transducer which was cleared on LOGIQ P9 and LOGIQ P7 (K163596). Two new applications are being added to this probe.
- New automated features are being added to assist the user workflow.
- The embedded operating system used is Windows 10, which is latest version introduced by Microsoft.
- The Venue and predicates Venue 50 (K152758) and LOGIQ e (K151028) 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 50 (K152758) 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
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, 2004
- 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), 2011

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).