



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

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

November 18, 2015

Re: K152758  
Trade/Device Name: Venue 50  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: September 23, 2015  
Received: September 24, 2015

Dear Ms. 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.

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” (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.

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 yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a slight shadow effect behind the letters.

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure



GE Healthcare  
510(k) Premarket Notification Submission

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

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

**Indications for Use**

510(k) Number (if known)

**K152758**

Device Name

Venue 50

Indications for Use (Describe)

The Venue 50 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Ophthalmic; Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Transvaginal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



**Diagnostic Ultrasound Indications for Use Form**  
**GE Venue 50 Ultrasound System**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse <sup>b</sup>	Other
			PW	CW	Color	Color M	Power				
<i>Anatomy/Region of Interest</i>											
Ophthalmic	P	P			P		P	P	P		
Fetal/OB	P	P			P		P	P	P		
Abdominal <sup>[1]</sup>	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify) <sup>[2]</sup>	P	P			P		P	P	P		
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic	P	P			P		P	P	P		
Cardiac <sup>[3]</sup>	P	P			P		P	P	P		
Peripheral Vascular	P	P			P		P	P	P		
Musculo-skeletal Conventional	P	P			P		P	P	P		
Musculo-skeletal Superficial	P	P			P		P	P	P		N <sup>[7]</sup>
Thoracic/Pleural (specify) <sup>[4]</sup>	P	P			P		P	P	P		
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal	P	P			P		P	P	P		
Intraoperative (specify) <sup>[5]</sup>	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		N <sup>[7]</sup>
Vascular Access (IV, PICC)	P	P			P		P	P	P		N <sup>[7]</sup>
Nonvascular (specify) <sup>[6]</sup>	P	P			P		P	P	P		N <sup>[7]</sup>

**N = new indication; P= previously cleared by FDA K133431**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Intraoperative includes abdominal, thoracic and peripheral;  
 [6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;  
 [7] Needle guidance with Pinpoint™ GT needle technology;  
 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Venue 50 with 12L-SC Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse <sup>b</sup>	Other
			PW	CW	Color	Color M	Power				
Ophthalmic	P	P			P		P	P	P		
Fetal/OB											
Abdominal <sup>[1]</sup>	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify) <sup>[2]</sup>	P	P			P		P	P	P		
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P			P		P	P	P		
Musculo-skeletal Conventional	P	P			P		P	P	P		
Musculo-skeletal Superficial	P	P			P		P	P	P		
Thoracic/Pleural (specify) <sup>[4]</sup>	P	P			P		P	P	P		
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify) <sup>[5]</sup>	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		
Vascular Access (IV, PICC)	P	P			P		P	P	P		
Nonvascular (specify) <sup>[6]</sup>	P	P			P		P	P	P		

**N = new indication; P= previously cleared by FDA K133431**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Intraoperative includes abdominal, thoracic and peripheral;  
 [6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;  
 [7] Needle guidance with Pinpoint™ GT needle technology;  
 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE Venue 50 with 3S-SC Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation									
	B	M	Doppler Modes				Combined Modes*	Harmonic Imaging	Coded Pulse <sup>b</sup>	Other
			PW	CW	Color	Color M				
Ophthalmic	P	P			P		P	P	P	
Fetal/OB	P	P			P		P	P	P	
Abdominal <sup>[1]</sup>	P	P			P		P	P	P	
Pediatric	P	P			P		P	P	P	
Small Organ (specify) <sup>[2]</sup>										
Neonatal Cephalic	P	P			P		P	P	P	
Adult Cephalic	P	P			P		P	P	P	
Cardiac <sup>[3]</sup>	P	P			P		P	P	P	
Peripheral Vascular										
Musculo-skeletal Conventional	P	P			P		P	P	P	
Musculo-skeletal Superficial										
Thoracic/Pleural (specify) <sup>[4]</sup>	P	P			P		P	P	P	
Other (specify)										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Intraoperative (specify) <sup>[5]</sup>	P	P			P		P	P	P	
Intraoperative Neurological										
Intravascular/Intraluminal										
<i>Interventional Guidance</i>										
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P	
Vascular Access (IV, PICC)										
Nonvascular (specify) <sup>[6]</sup>										

**N = new indication; P= previously cleared by FDA K133431**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Intraoperative includes abdominal, thoracic and peripheral;  
 [6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;  
 [7] Needle guidance with Pinpoint™ GT needle technology;  
 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE Venue 50 with 4C-SC Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation									
	B	M	Doppler Modes				Combined Modes*	Harmonic Imaging	Coded Pulse <sup>b</sup>	Other
			PW	CW	Color	Color M				
Ophthalmic										
Fetal/OB	P	P			P		P	P		
Abdominal <sup>[1]</sup>	P	P			P		P	P		
Pediatric	P	P			P		P	P		
Small Organ (specify) <sup>[2]</sup>										
Neonatal Cephalic										
Adult Cephalic										
Cardiac <sup>[3]</sup>										
Peripheral Vascular										
Musculo-skeletal Conventional	P	P			P		P	P		
Musculo-skeletal Superficial										
Thoracic/Pleural (specify) <sup>[4]</sup>	P	P			P		P	P		
Other (specify)										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Intraoperative (specify) <sup>[5]</sup>	P	P			P		P	P		
Intraoperative Neurological										
Intravascular/Intraluminal										
<i>Interventional Guidance</i>										
Tissue Biopsy/Fluid Drainage	P	P			P		P	P		
Vascular Access (IV, PICC)										
Nonvascular (specify) <sup>[6]</sup>	P	P			P		P	P		

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- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Intraoperative includes abdominal, thoracic and peripheral;  
 [6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;  
 [7] Needle guidance with Pinpoint™ GT needle technology;  
 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Venue 50 with L8-18i-SC Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>b</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal/OB											
Abdominal <sup>[1]</sup>	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify) <sup>[2]</sup>	P	P			P		P	P	P		
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P			P		P	P	P		
Musculo-skeletal Conventional	P	P			P		P	P	P		
Musculo-skeletal Superficial	P	P			P		P	P	P		
Thoracic/Pleural (specify) <sup>[4]</sup>	P	P			P		P	P	P		
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify) <sup>[5]</sup>	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		
Vascular Access (IV, PICC)	P	P			P		P	P	P		
Nonvascular (specify) <sup>[6]</sup>	P	P			P		P	P	P		

**N = new indication; P= previously cleared by FDA K133431**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Intraoperative includes abdominal, thoracic and peripheral;  
 [6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;  
 [7] Needle guidance with Pinpoint™ GT needle technology;  
 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE Venue 50 with E8CS-SC Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	Doppler Modes				Combined Modes*	Harmonic Imaging	Coded Pulse <sup>b</sup>	Other	
			PW	CW	Color	Color M					Power
Ophthalmic											
Fetal/OB	P	P			P		P	P	P		
Abdominal <sup>[1]</sup>	P	P			P		P	P	P		
Pediatric											
Small Organ (specify) <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) <sup>[4]</sup>											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal	P	P			P		P	P	P		
Intraoperative (specify) <sup>[5]</sup>											
Intraoperative Neurological											
Intravascular/Intraluminal											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P		
Vascular Access (IV, PICC)											
Nonvascular (specify) <sup>[6]</sup>											

**N = new indication; P= previously cleared by FDA K133431**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Intraoperative includes abdominal, thoracic and peripheral;  
 [6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;  
 [7] Needle guidance with Pinpoint™ GT needle technology;  
 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Venue 50 with 10C-SC Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse <sup>7</sup>	Other
			PW	CW	Color	Color M	Power				
<i>Anatomy/Region of Interest</i>											
Ophthalmic	P	P			P		P	P	P		
Fetal/OB											
Abdominal <sup>[1]</sup>	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ (specify) <sup>[2]</sup>	P	P			P		P	P	P		
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	P	P			P		P	P	P		
Thoracic/Pleural (specify) <sup>[4]</sup>	P	P			P		P	P	P		
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify) <sup>[5]</sup>	P	P			P		P	P	P		
Intraoperative Neurological											
Intravascular/Intraluminal											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage											
Vascular Access (IV, PICC)											
Nonvascular (specify) <sup>[6]</sup>											

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- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Intraoperative includes abdominal, thoracic and peripheral;  
 [6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;  
 [7] Needle guidance with Pinpoint™ GT needle technology;  
 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Venue 50 with L12n-SC Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse <sup>b</sup>	Other
			PW	CW	Color	Color M	Power				
<i>Anatomy/Region of Interest</i>											
Ophthalmic	N	N			N		N	N	N		
Fetal/OB											
Abdominal <sup>[1]</sup>	N	N			N		N	N	N		
Pediatric	N	N			N		N	N	N		
Small Organ (specify) <sup>[2]</sup>	N	N			N		N	N	N		
Neonatal Cephalic	N	N			N		N	N	N		
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	N	N			N		N	N	N		
Musculo-skeletal Conventional	N	N			N		N	N	N		
Musculo-skeletal Superficial	N	N			N		N	N	N	N <sup>[7]</sup>	
Thoracic/Pleural (specify) <sup>[4]</sup>	N	N			N		N	N	N		
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify) <sup>[5]</sup>	N	N			N		N	N	N		
Intraoperative Neurological											
Intravascular/Intraluminal											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	N	N			N		N	N	N	N <sup>[7]</sup>	
Vascular Access (IV, PICC)	N	N			N		N	N	N	N <sup>[7]</sup>	
Nonvascular (specify) <sup>[6]</sup>	N	N			N		N	N	N	N <sup>[7]</sup>	

**N = new indication; P= previously cleared by FDA K133431**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
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 [\*] Combined modes are color/power Doppler with B-mode

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**510(k) Summary**

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

Date: September 23,2015  
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: Yalan Wu  
Regulatory Affairs  
GE Medical Systems (China) Co, Ltd.  
T: +86 510 8527 8652  
F: +86 510 8522 7347

Device: Trade Name: Venue 50

Common/Usual Name: 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

Predicate Device(s): Venue 50 - K133431  
Site~Rite® 6 Ultrasound System – K142443

Device Description: The Venue 50 device is a compact and portable ultrasound system consisting of a hand-carried console (tablet sized) with the ability to dock it with a Docking station or mobile Docking cart. The portable design easily fits into tight spaces. High-resolution imaging, transducer options and wide range of applications help physicians care for a broad spectrum of patients. The single-surface screen can be disinfected and cleaned with medical grade disinfectants. Flexible data management and connectivity options, with optional DICOM, help speed image storage and archiving for physicians at the Point of Care and patient bedside.

Intended Use: The Venue 50 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Ophthalmic; Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal



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Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Transvaginal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

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 50 employs the same fundamental scientific technology as its predicate devices.

#### Determination of Substantial Equivalence:

#### Comparison to Predicates

The Venue 50 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 diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Venue 50 and predicate Venue 50 system have the same clinical intended use
- The proposed Venue 50 and predicate Venue 50 system have the same imaging modes.
- The transducers of proposed Venue 50 and predicate Venue 50 system are the same except for:
  - Adding L12n-SC, it is a linear transducer similar to the 12L-SC that was cleared on the predicate Venue 50 system (K133431). The L12n-SC includes programmable buttons and works with the Pinpoint™ GT Technology.
- Utilization of the Pinpoint GT Technology from C.R. Bard, which allows the user to track the needle location during interventional guidance. This technology is equivalent to that cleared by C.R. Bard, Inc. in K142443.
- Addition of data privacy features includes internal storage encryption, which allows the user to encrypt patient data, and a passcode requirement to unlock the screen.
- The proposed Venue 50 and predicate Venue 50 system are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.



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- The proposed Venue 50 and predicate Venue 50 system have acoustic power levels which are below the applicable FDA limits.
- The proposed Venue 50 and predicate Venue 50 system have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Venue 50 and predicate Venue 50 system have been designed in compliance with approved electrical and physical safety standards.

### Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. The Venue 50 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- ISO14971, Application of risk management to medical devices
- NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)



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The following quality assurance measures were 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)
- Simulated use Testing (Validation)

Transducer materials and other patient contact materials are biocompatible.

### Summary of Clinical Tests:

The subject of this premarket submission, Venue 50, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Venue 50 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).