AUG 1 2 2010

K102113

Attachment B

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

GE Medical Systems (China) Co., Ltd
No. 19 Changjiang Road, National Hi-Tech Development Zone
Wuxi, Jiangsu Province, CHINA 214028

Section a):

1. Submitter: GE Medical Systems (China) Co., Ltd.
No. 19 Changjiang Road, National Hi-Tech Development Zone, Wuxi, Jiangsu Province, CHINA 214028

Contact Person: Yalan Wu,
Manager, Safety and Regulatory
Telephone: 86-510-85278652; Fax: 86-510-85227347

Date Prepared: July 8, 2010

2. Device Name: GE Venue 40 Ultrasound
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX

3. Marketed Device: GE LOGIQ e Diagnostic Ultrasound K091374, GE Venue 40 Diagnostic Ultrasound K091164 (90-IYO/IYN/ITX) A device currently in commercial distribution.

4. Device Description: The Venue 40 device is a compact and extremely portable ultrasound system consisting of a hand-carried console with the ability to dock it with a stand or mobile cart. The primary means of control is a small number of dedicated push buttons and graphical user interface implemented by a touch sensitive screen over the color LCD display. It utilizes interchangeable electronic-array transducers with digital acquisition, processing and display capability operating. Powered by an integrated battery or from a separate power supply/charger in the docking station or docking cart, the Venue 40 is used primarily where portability, size and convenience are essential.

5. Indications for Use: The Venue 40 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculo-skeletal Conventional & Superficial; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

6. Comparison with Predicate Device: The GE Venue 40 is of a comparable type and substantially equivalent to the current GE LOGIQ e with overall performance in a small and compact package. It has the same overall characteristics, key safety and effectiveness features, physical design, general overall construction, and materials, and has the less intended uses and operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE Venue 40 Ultrasound imaging device is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ge Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 12 2010

Re: K102113
Trade/Device Name: GE Venue 40 Diagnostic Ultrasound
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 27, 2010
Received: July 28, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Venue 40 Diagnostic Ultrasound, as described in your premarket notification:

Transducer Model Number

12L-SC
3S-SC
4C-SC
L8-18i-SC

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Andrew Kang at (301) 796-6544.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

510(k) Number (if known): K102113

AUG 12 2010

Device Name: GE Venue 40 Diagnostic Ultrasound

Indications For Use:

The Venue 40 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

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Concurrence of CDRH, Office of In Vitro Diagnostics

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102113

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 Ultrasound

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

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;
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102113

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with 12L-SC Transducer

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

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
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102113

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with 3S-SC Transducer

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

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
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Prescription Use (21 CFR 801 Subpart D)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102113

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with 4C-SC Transducer

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

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
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102113

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with L8-18i-SC Transducer

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Prescription Use (21 CFR 801 Subpart D)

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