DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 31, 2016

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

Re: K161588
Trade/Device Name: Vscan Extend
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 10, 2016
Received: August 11, 2016

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,

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K161588

Device Name
Vscan Extend

Indications for Use *(Describe)*

Vscan Extend is a general purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid. It's pocket-sized portability and simplified user interface enables integration into examination and training sessions indoors and in other environments described in the user manual. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic monitoring, and triage.

With the phased array transducer on the sector probe, the specific clinical applications and exam types include: Cardiac; Abdominal; Renal; OB/GYN; Urology; Fetal, Evaluation of Presence of Fluid; Imaging Guidance for Needle/Catheter Placement (e.g. paracentesis, pericardiocentesis, thoracentesis, amniocentesis); Peripheral Vascular Imaging (e.g. arteries and veins); Thoracic/Lung (e.g. pleural motion/sliding, line artifacts); Adult Cephalic; and Pediatrics.

With the addition of the linear array transducer on the single dual headed probe solution, the specific clinical applications and exam types are expanded to include: Peripheral vascular imaging (e.g. lower extremity, carotid); Procedure Guidance for Arterial or Venous Vessels (e.g. central lines, upper extremity); Small Organs (e.g. thyroid); and Musculoskeletal (Long Bone; Hip, shoulder, elbow and Knee Joints); Evaluation of Presence of Fluid; Thoracic/Lung (e.g. pleural motion/sliding, line artifacts); and Pediatrics.

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)*

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:

Department of Health and Human Services
Food and Drug Administration
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PRAStaff@fda.hhs.gov

"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."

Diagnostic Ultrasound Indications for Use Form
Vscan Extend Ultrasound System

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	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Fetal/OB	N				N			N	N		7
Abdominal[1]	N				N			N	N		7
Pediatric	N				N			N	N		7
Small Organ[2]	N				N			N			7
Neonatal Cephalic											
Adult Cephalic	N				N			N	N		
Cardiac Adult	N				N			N	N		7
Cardiac Pediatric	N				N			N	N		7
Peripheral Vascular[3]	N				N			N	N		7
Musculo-skeletal Conventional[4]	N				N			N			7
Musculo-skeletal Superficial											
Thoracic/Pleural [5]	N				N			N	N		7
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Vascular Access[6]	N				N			N			7
Nonvascular	N				N			N	N		7

N = new indication; P= previously cleared by FDA in K140693

Notes:

[1] Abdominal includes Gynecology, Renal and Urology;
[2] Small Organ includes thyroid;
[3] Peripheral Vascular includes arteries and veins, lower extremity, carotid;
[4] Musculo-skeletal Conventional includes long bone, hip, shoulder, elbow and knee joint visualization;
[5] Thoracic/Pleural is pleural motion/sliding, line artifacts as well as fluid detection;
[6] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[7] Image guidance for freehand needle/catheter placement;
[*] Combined mode is B/Color.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Diagnostic Ultrasound Indications for Use Form

Vscan Extend with deep scanning-phased array transducer (G3S)

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	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Fetal/OB	P				P			P	P		7
Abdominal[1]	P				P			P	P		7
Pediatric	P				P			P	P		7
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	N				N			N	N		
Cardiac Adult	P				P			P	P		7
Cardiac Pediatric	P				P			P	P		7
Peripheral Vascular[3]	P				P			P	P		7
Musculo-skeletal Conventional[4]											
Musculo-skeletal Superficial											
Thoracic/Pleural [5]	P				P			P	P		7
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Vascular Access[6]											
Nonvascular	P				P			P	P		7

N = new indication; P= previously cleared by FDA in K140693

Notes:

[1] Abdominal includes Gynecology, Renal and Urology;
[2] Small Organ includes thyroid;
[3] Peripheral Vascular includes arteries and veins, lower extremity, carotid;
[4] Musculo-skeletal Conventional includes long bone, hip, shoulder, elbow and knee joint visualization;
[5] Thoracic/Pleural is pleural motion/sliding, line artifacts as well as fluid detection;
[6] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[7] Image guidance for freehand needle/catheter placement;
[*] Combined mode is B/Color.

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

Diagnostic Ultrasound Indications for Use Form

Vscan Extend with shallow scanning-linear array transducer (G8L)

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	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Fetal/OB											
Abdominal[1]											
Pediatric	P				P			P			7
Small Organ[2]	P				P			P			7
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular[3]	P				P			P			7
Musculo-skeletal Conventional[4]	P				P			P			7
Musculo-skeletal Superficial											
Thoracic/Pleural [5]	P				P			P			7
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Vascular Access[6]	P				P			P			7
Nonvascular [7]											

N = new indication; P= previously cleared by FDA in K140693

Notes:

[1] Abdominal includes Gynecology, Renal and Urology;
[2] Small Organ includes thyroid;
[3] Peripheral Vascular includes arteries and veins, lower extremity, carotid;
[4] Musculo-skeletal Conventional includes long bone, hip, shoulder, elbow and knee joint visualization;
[5] Thoracic/Pleural is pleural motion/sliding, line artifacts as well as fluid detection;
[6] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[7] Image guidance for freehand needle/catheter placement;
[*] Combined mode is B/Color.

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

510(k) Summary

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

Date:	June 7, 2016
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 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:	Sadashiva Subraya Regulatory Affairs Leader GE Healthcare T: +91 80 4088 2969
Device: Trade Name:	Vscan Extend
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
Primary Predicate Device(s):	Vscan with Dual Probe - K140693
Reference Predicate Device(s):	Venue 50 – K152758 Venue 40 – K112122
Device Description:	Vscan Extend is a pocket-sized, battery powered general purpose, track 3, diagnostic ultrasound system. The system consists of a handheld unit with a 5 inch touch screen display and a permanently attached probe. The probe is available in one of two configurations: a sector probe with phased array transducer or both phased and linear array transducers in the single probe (dual probe). It has digital acquisition, processing and display capabilities. The device specific battery can be charged either in the system or independently. The system also may include an AC/DC adapter with cable, case, Micro SD card, USB cable, or other accessories.

The system is capable of transferring images wirelessly to a DICOM server or Windows share. Data can also be exported to the user's computer by using the USB export option and a standard USB/micro USB cable. Capabilities also include access to GE Marketplace, which shall allow the user to download software applications to the device.

Intended Use: Vscan Extend is a general purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid. It's pocket-sized portability and simplified user interface enables integration into examination and training sessions indoors and in other environments described in the user manual. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic monitoring, and triage.

With the phased array transducer on the sector probe, the specific clinical applications and exam types include: Cardiac; Abdominal; Renal; OB/GYN; Urology; Fetal, Evaluation of Presence of Fluid; Imaging Guidance for Needle/Catheter Placement (e.g. paracentesis, pericardiocentesis, thoracentesis, amniocentesis); Peripheral Vascular Imaging (e.g. arteries and veins); Thoracic/Lung (e.g. pleural motion/sliding, line artifacts); Adult Cephalic; and Pediatrics.

With the addition of the linear array transducer on the single dual headed probe solution, the specific clinical applications and exam types are expanded to include: Peripheral vascular imaging (e.g. lower extremity, carotid); Procedure Guidance for Arterial or Venous Vessels (e.g. central lines, upper extremity); Small Organs (e.g. thyroid); and Musculoskeletal (Long Bone; Hip, shoulder, elbow and Knee Joints); Evaluation of Presence of Fluid; Thoracic/Lung (e.g. pleural motion/sliding, line artifacts); and Pediatrics.

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

Determination of Substantial Equivalence:

Comparison to Predicates

The Vscan Extend is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technologicial characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Vscan Extend and predicate Vscan with Dual Probe have the same clinical intended use and clinical applications except that addition of adult cephalic that was cleared on the Venue 40 predicate.
- The proposed Vscan Extend and predicate Vscan with Dual Probe have the same imaging modes.
- The proposed Vscan Extend and predicate Vscan with Dual Probe are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The proposed Vscan Extend and predicate device Vscan with Dual Probe have the same phased array transducer for deep scanning and linear array transducer for shallow scanning.
- The proposed Vscan Extend and predicate Vscan with Dual Probe have similar acoustic power levels. All values are below FDA applicable limits.
- The proposed Vscan Extend and predicate Vscan with Dual Probe have the same capability in terms of performing measurements, capturing digital images and reviewing the images.
- The proposed Vscan Extend has WiFi connectivity similar to the predicate device Venue 50.
- The proposed Vscan Extend and predicate device Venue 50 system have same data privacy features including internal storage encryption which allows the user to encrypt patient data.
- The proposed Vscan Extend has DICOM connectivity similar to the predicate device Venue 50.
- The proposed Vscan Extend and predicate systems 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 Vscan Extend and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety and Essential Performance, 2005
- IEC60601-1-2,Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2007
- 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: Second edition, 2007
- NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

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)
- Verification of Privacy & Security Design

Transducer materials are biocompatible.

Summary of Clinical Tests:

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

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