MAY 16 2014

K140693

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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:	May 15, 2014
Submitter:	GE Healthcare GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC 9900 Innovation Drive Wauwatosa, WI 53226
Manufacturer:	GE Vingmed Ultrasound AS Strandpromenaden 45 Horten, Norway N-3183
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)676-6120 F:(414)918-8275
Alternate Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Device Trade Name:	Vscan with Dual Probe
Common Name:	Ultrasound system
Classification:	Class II
Classification Name / 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):	Vscan Diagnostic Ultrasound System - K092756 Vivid e Diagnostic Ultrasound System - K113690 Venue 40 Diagnostic Ultrasound System - K112122

Technology: The Vscan with Dual Probe employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The Vscan with Dual Probe system is substantially equivalent to the predicate devices with regard 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 Vscan with Dual Probe and predicate Vscan system have the same clinical intended use with the exception of Small Organ, Musculo-skeletal conventional, Vascular access and Nonvascular access. Small Organ, Musculo-skeletal conventional clinical intended uses are substantially equivalent to Vivid e in K113690. Vascular access and nonvascular access intended uses are substantially equivalent to the intended use Venue 40 cleared in K112122.
- The Vscan with Dual Probe and predicate Vscan have the same imaging modes.
- The Vscan with Dual Probe and predicate Vscan have the same system display size and are battery powered.
- The deep scanning end of the transducer on Vscan with Dual Probe is similar to the probe on Vscan cleared in K092756.
- The shallow scanning end of the transducer on Vscan with Dual Probe is similar to the 8L-RS probe used on and cleared with Vivid e in K113690.
- The systems are 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 Vscan with Dual Probe and predicate Vscan have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The Vscan with Dual Probe and predicate systems have been designed in compliance with approved electrical and physical safety standards.

Device Description: Vscan with Dual Probe is a pocket-sized, battery powered general purpose, track 3, diagnostic ultrasound system. The system consists of a handheld unit with a flip up 3.5 inch LCD display and a permanently attached dual ended (phased and linear) transducer operating B and color modes with digital acquisition, processing and display capability. The user interface control panel is composed of a navigation wheel that allows for intuitive thumb control.

The battery can be charge either in the system or alone. The system contains a Docking Station, charger with cable and soft bag. Capabilities also include distance measurements, voice recordings and storage of files. Additional Vscan gateway software can be loaded on a personal computer to allow the user to review, annotate and create reports with the image, video and voice files once files are transferred using the included USB cable.

Intended Use: Vscan with Dual Probe is general purpose diagnostic ultrasound imaging system for use by qualified and trained health care professionals enabling visualization and measurement of anatomical structures and fluid. With a single probe solution, the dual headed probe integrates both linear and phased array transducers that allows for a wide range of clinical applications: Cardiac; Abdominal; Renal; OB/GYN; Urology; Fetal, Evaluation of Presence of Fluid; Peripheral Vascular Imaging(e.g. lower extremity, carotid); Procedure Guidance for Arterial or Venous Vessels(e.g. central lines, upper extremity); Imaging Guidance for Needle/Catheter Placement(e.g. paracentesis, thoracentesis, amniocentesis); Thoracic/Lung(e.g. pleural motion/sliding, line artifacts); Thyroid and other Small Organs; Long Bone; Hip and Knee Joints; and Pediatrics

Its 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, triage assessments, and procedural guidance for adults and pediatrics.

Summary of Non-Clinical Tests:
The device 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 conform with applicable medical device safety standards. The Vscan with Dual Probe and its applications will comply with voluntary standards:

- AAMI/ANSI ES60601-1 (includes IEC 60601-1), 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- Third Edition
- ISO14971, Application of risk management to medical devices
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

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)

Transducer materials are biocompatible.

Summary of Clinical Tests:

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

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

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

May 16, 2014

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

Re: K140693
Trade/Device Name: Vscan with Dual Probe
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: March 19, 2014
Received: March 20, 2014

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Vscan With Dual Probe, as described in your premarket notification:

Transducer Model Number	
G3S	G8L

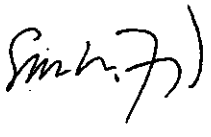
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



for

Janine M. Morris
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)*
K140693

Device Name
Vscan with Dual Probe

Indications for Use *(Describe)*

Vscan with Dual Probe is general purpose diagnostic ultrasound imaging system for use by qualified and trained health care professionals enabling visualization and measurement of anatomical structures and fluid. With a single probe solution, the dual headed probe integrates both linear and phased array transducers that allows for a wide range of clinical applications:
Cardiac; Abdominal; Renal; OB/GYN; Urology; Fetal, Evaluation of Presence of Fluid; Peripheral Vascular Imaging(e.g. lower extremity, carotid); Procedure Guidance for Arterial or Venous Vessels(e.g. central lines, upper extremity); Imaging Guidance for Needle/Catheter Placement(e.g. paracentesis, thoracentesis, amniocentesis); Thoracic/Lung(e.g. pleural motion/sliding, line artifacts); Thyroid and other Small Organs; Long Bone; Hip and Knee Joints; and Pediatrics

Its 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, triage assessments, and procedural guidance for adults and pediatrics.

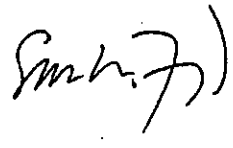
Type of Use *(Select one or both, as applicable)*

☒ 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
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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 with Dual Probe Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow 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		
Abdominal[1]	N				N			N	N		
Pediatric	N				N			N	N		
Small Organ[2]	N				N			N			
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult	N				N			N	N		
Cardiac Pediatric	N				N			N	N		
Peripheral Vascular[3]	N				N			N	N		
Musculo-skeletal Conventional[4]	N				N			N			
Musculo-skeletal Superficial											
Thoracic/Pleural[5]	N				N			N	N		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Vascular Access[6]	N				N			N			
Nonvascular[7]	N				N			N	N		

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Gynecology, Renal and Urology;
[2] Small Organ includes breast, testes, and thyroid;
[3] Peripheral Vascular includes arteries and veins;
[4] Musculo-skeletal Conventional includes long bone, hip and knee joint visualization;
[5] Thoracic/Pleural is pleural motion/sliding as well as fluid detection;
[6] Vascular Access includes intravenous, intra-arterial, central and peripheral lines;
[7] Nonvascular is 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 with Dual Probe with deep scanning transducer (G3S)

Intended Use: Diagnostic Ultrasound imaging or fluid flow 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		
Abdominal[1]	P				P			P	P		
Pediatric	P				P			P	P		
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult	P				P			P	P		
Cardiac Pediatric	P				P			P	P		
Peripheral Vascular[3]	P				N			N	P		
Musculo-skeletal Conventional[4]											
Musculo-skeletal Superficial											
Thoracic/Pleural[5]	P				P			P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Vascular Access[6]											
Nonvascular[7]	N				N			N	N		

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Gynecology, Renal and Urology;
[2] Small Organ includes breast, testes, and thyroid;
[3] Peripheral Vascular includes arteries and veins;
[4] Musculo-skeletal Conventional includes long bone, hip and knee joint visualization;
[5] Thoracic/Pleural is pleural motion/sliding as well as fluid detection;
[6] Vascular Access includes intravenous, intra-arterial, central and peripheral lines;
[7] Nonvascular is 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 with Dual Probe with shallow scanning transducer (G8L)

Intended Use: Diagnostic Ultrasound imaging or fluid flow 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	N				N			N			
Small Organ[2]	N				N			N			
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular[3]	N				N			N			
Musculo-skeletal Conventional[4,6]	N				N			N			
Musculo-skeletal Superficial[5]											
Thoracic/Pleural[6]	N				N			N			
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Vascular Access[7]	N				N			N			
Nonvascular[8]	N				N			N			

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Gynecology, Renal and Urology;
[2] Small Organ includes breast, testes, and thyroid;
[3] Peripheral Vascular includes arteries and veins;
[4] Musculo-skeletal Conventional includes long bone, hip and knee joint visualization;
[5] Thoracic/Pleural is pleural motion/sliding as well as fluid detection;
[6] Vascular Access includes intravenous, intra-arterial, central and peripheral lines;
[7] Nonvascular is 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)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) Number_____