K092756

Attachment B

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

SEP 2 8 2009

Section a):

1. Submitter: GE Vingmed Ultrasound AS
Strandpromenaden 45
N-3183, Horten, Norway

Contact Person: Jan Tore Thollefsen,
Regulatory Affairs Leader
Telephone: +47 3302 1269; Fax: 972-4-8519-500

Date Prepared: July 13, 2009

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

3. Marketed Devices: GE Vivid-e Ultrasound System, K072797 currently in commercial distribution.
GE Venue 40 Ultrasound System, K091164 currently in commercial distribution.
Acuson P10 Ultrasound System, K063761 currently in commercial distribution.

4. Device Description: The GE Vscan is compact and portable diagnostic ultrasound system with integrated keyboard, fold-up LCD type display and fixed wired electronic-array transducer. It has an overall size approximately 73 mm wide, 135 mm deep and 28 mm high in transport configuration, and provides digital acquisition, processing and display capability. The user interface includes an intuitive layout of specialized controls and a color LCD display.

5. Indications for Use: The GE Vscan is indicated for ultrasound imaging, measurement and analysis of the human body in clinical applications of Fetal/OB; Abdominal; Pediatric; Urology; Cardiac (adult and pediatric), Peripheral Vessel and Thoracic/Pleural motion and fluid detection; Its compact size, high degree of portability and simplified user interface enable it for adjunctive use for patient examination in primary care and in special care areas.

6. Comparison with Predicate Device: The modified GE Vscan is of a comparable type and substantially equivalent to the currently marketed GE Vivid e, GE Venue 40 and Acuson P10. It is a compact and readily portable unit comparable in key safety and effectiveness features and with the same patient contact materials as currently marketed transducer. GE Vscan has the same intended uses as the predicate devices.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness 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 to 21 CFR 820, ISO 9001 and ISO13485 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 Medical Systems that the GE Vscan Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 2 8 2009

GE Vingmed Ultrasound AS
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K092756
Trade/Device Name: GE Vscan-Compact Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 8, 2009
Received: September 9, 2009

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 Vscan-Compact Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

G3S

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 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); 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 Shahram Vaezy at (301) 796-6242.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

GE Vscan Ultrasound System

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

Clinical Application		Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic	Ophthalmic											
Fetal Imaging & Other	Fetal	N				N			N	N		
	Abdominal[1]	N				N			N	N		
	Intra-operative (Specify)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric	N				N			N	N		
	Small Organ (specify)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph.(non-Card.)											
	Musculo-skeletal Conventional											
	Musculo-skeletal Superficial											
	Intravascular											
	Other (specify)[2]	N				N			N	N		
Cardiac	Cardiac Adult	N				N			N	N		
	Cardiac Pediatric	N				N			N	N		
	Intravascular (Cardiac)											
	Trans-esoph.(Cardiac)											
	Intra-cardiac											
	Other (specify)											
Peripheral Vessel	Peripheral vessel	N								N		
	Other (specify)											

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

Notes: [1] Abdominal includes Renal.

[2] Other use includes Urology and Thoracic/Pleural detection of fluid and pleural motion/sliding.

[*] Combined mode is B/Color.

[♦] Coded Pulse is for digitally encoded harmonics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K092756

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vscan Ultrasound System with G3S transducer

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

Clinical Application		Mode of Operation										
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♭	Other
Ophthalmic	Ophthalmic											
Fetal Imaging & Other	Fetal	N				N			N	N		
	Abdominal[1]	N				N			N	N		
	Intra-operative (Specify)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric	N				N			N	N		
	Small Organ (specify)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph.(non-Card.)											
	Musculo-skeletal Conventional											
	Musculo-skeletal Superficial											
	Intravascular											
	Other (specify)[2]	N				N			N	N		
Cardiac	Cardiac Adult	N				N			N	N		
	Cardiac Pediatric	N				N			N	N		
	Intravascular (Cardiac)											
	Trans-esoph.(Cardiac)											
	Intra-cardiac											
	Other (specify)											
Peripheral Vessel	Peripheral vessel	N								N		
	Other (specify)											

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

Notes: [1] Abdominal includes Renal.

[2] Other use includes Urology and Thoracic/Pleural detection of fluid and pleural motion/sliding.

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