Attachment B

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

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.
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](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](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 Shâhram Vaezy at (301) 796-6242.

Sincerely yours,

[Signature]

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:

<table>
<thead>
<tr>
<th>Clinical Application &amp; Other</th>
<th>Mode of Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>General (Track 1 Only)</td>
<td>B M PW CW Color Color M Power Combined Harmonic Coded Pulse Other</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Ophthalmic</td>
</tr>
<tr>
<td>Fetal</td>
<td>N</td>
</tr>
<tr>
<td>Abdominal[1]</td>
<td>N</td>
</tr>
<tr>
<td>Intra-operative (Specify)</td>
<td>N</td>
</tr>
<tr>
<td>Intra-operative (Neuro)</td>
<td>N</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>N</td>
</tr>
<tr>
<td>Pediatric</td>
<td>N</td>
</tr>
<tr>
<td>Pediatric (specify)</td>
<td>N</td>
</tr>
<tr>
<td>Neonatal Cephalic</td>
<td>N</td>
</tr>
<tr>
<td>Adult Cephalic</td>
<td>N</td>
</tr>
<tr>
<td>Trans-rectal</td>
<td>N</td>
</tr>
<tr>
<td>Trans-vaginal</td>
<td>N</td>
</tr>
<tr>
<td>Trans-urethral</td>
<td>N</td>
</tr>
<tr>
<td>Trans-oph (non-Card.)</td>
<td>N</td>
</tr>
<tr>
<td>Musculo-skeletal Conventional</td>
<td>N</td>
</tr>
<tr>
<td>Musculo-skeletal Superficial</td>
<td>N</td>
</tr>
<tr>
<td>Intra-vascular</td>
<td>N</td>
</tr>
<tr>
<td>Other (specify)[2]</td>
<td>N</td>
</tr>
<tr>
<td>Cardio (Specify)</td>
<td>N</td>
</tr>
<tr>
<td>Cardio Pediatric</td>
<td>N</td>
</tr>
<tr>
<td>Intravascular (Cardiac)</td>
<td>N</td>
</tr>
<tr>
<td>Trans-oph (Cardiac)</td>
<td>N</td>
</tr>
<tr>
<td>Intra-cardiac</td>
<td>N</td>
</tr>
<tr>
<td>Other (specify)</td>
<td>N</td>
</tr>
<tr>
<td>Peripheral Vessel</td>
<td>N</td>
</tr>
<tr>
<td>Other (specify)</td>
<td>N</td>
</tr>
</tbody>
</table>

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.
3. Combined mode is B/Color.
4. Coded Pulse is for digitally encoded harmonics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

E-2

Division of Reproductive, Abdominal, and Radiological Devices.

510(k) Number: K09276
## 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:

<table>
<thead>
<tr>
<th>General Application</th>
<th>Mode of Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific (Track 1 &amp; 3)</td>
<td>General Specific BM PW CW Color Color M Power Combined Harmonic Coded Other</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Ophthalmic</td>
</tr>
<tr>
<td>Fetal Imaging &amp; Other</td>
<td>Fetal Abdominal(1) Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric 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) Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-cardiac Other (specify) Peripheral Vessel Peripheral vessel Other (specify)</td>
</tr>
</tbody>
</table>

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.  
3. Combined mode is B/Color.  
4. Coded Pulse is for digitally encoded harmonics.

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### Prescription User (Per 21 CFR 801.109)

Division Sign-Off:  
Division of Reproductive, Abdominal, and Radiological Devices  
510(k) Number K092756