Section aj:

1. **Submitter:** GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC, a division of the General Electric Company
   GE Medical Systems Lunar (business name)
   726 Heartland Trail
   Madison, WI 53717

   **Contact Person:** James P. Raskob
   Safety and Regulatory Engineering Manager
   Telephone: 608-826-7425; Fax: 608-299-2132.

   **Date Prepared:** August 12, 2008

2. **Device Name:** GE Lunar FRAX™ 10-year fracture risk software option
   Bone Densitometer, 21 CFR 892.1170, 90-KGI

3. **Marketed Device:** Fracture Risk for DPX bone densitometers K983271
   Fracture Risk from BMD using Hologic QDR x-ray Bone Densitometers K983028

4. **Device Description:** The FRAX™ 10-Year Fracture Risk software option for GE Lunar Bone
   densitometers provides a 10-year fracture risk assessment based on patient's bone
   mineral density T-score and clinical risk factors using the FRAX™ WHO Fracture
   Risk Assessment Tool.

5. **Indications for Use:** FRAX™ 10-Year Fracture Risk Software Option for GE Lunar Bone
   Densitometers

   The FRAX™ 10-Year Fracture Risk software option is an accessory to currently marketed GE Lunar
   bone densitometer devices, which are intended to estimate the bone mineral density and body
   composition (lean and fat tissue mass) of patients when medically indicated by their physicians.

   This software option is intended to provide an assessment of 10-year fracture risk. The option
   provides an estimate of 10-year probability of hip fracture and 10-year probability of a major
   osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on
   the patient’s age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence
   or absence of several risk factors and is computed using the FRAX™ Fracture Risk Assessment
   Tool endorsed by the World Health Organization (WHO). The tool has been validated for men and
   post-menopausal women between 40 and 90 years old. The output is provided in a separate screen
   display and report that can be viewed or printed or exported to an optional physician report generator
   tool.

   The results can be used by a physician in conjunction with other clinical risk factors as an aid in
   the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and
   ultimately in the assessment of fracture risk.
6. **Comparison with Predicate Device:** The GE Lunar FRAX™ 10-year Fracture Risk Software Option for GE Lunar DXA Bone Densitometers is of a comparable type and substantially equivalent to the Fracture Risk for DPX bone densitometers and Fracture Risk from BMD using Hologic QDR x-ray Bone Densitometers. It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction, and materials, and has similar intended uses as the predicate devices.

Section b):

1. **Non-clinical Tests:** The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. Design verification tests of the software option were performed using a series of test cases from published data. These tests confirmed outputs from the GE Lunar FRAX™ 10-year Fracture Risk Software were consistent with the independent outputs published that utilized the WHO 10-year fracture probability algorithm for specific age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence or absence of several clinical risk factors.

2. **Clinical Tests:** No new clinical studies were required to establish safety or effectiveness of the new software option. Published literature describing the development and clinical validation of the FRAX™ WHO Fracture Risk Assessment Tool were provided.

The FRAX™ model is based on a large collection of data. Appropriate clinical risk factors for fracture were determined from eleven large cohort studies. The FRAX™ model was then developed from baseline and follow up data from nine prospective, population-based cohorts, including centers in North America, Europe, Asia, and Australia, consisting of 46,340 people and 189,852 person years of follow-up, during which 850 hip fractures and 3318 other osteoporotic fractures were reported. Data were generally randomly selected and analyzed according to accepted epidemiological practices. All data were published in peer-reviewed journals.

The performance characteristics determined from the primary cohorts were then validated in eleven independent, population-based cohorts that did not participate in the model synthesis. The validation cohorts consisted of 230,486 subjects representing 1,208,528 patient years of follow-up, during which 3360 hip fractures and 15,183 other osteoporotic fractures occurred.

3. **Conclusion:** Intended uses and other key features are consistent with previously cleared bone densitometer fracture risk software options. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance was verified through ongoing internal and independent quality system audits. Therefore, the GE Lunar FRAX™ 10-year Fracture Risk Software Option for GE Lunar DXA Bone Densitometers is substantially equivalent to currently marketed devices with respect to intended use and safety and effectiveness.
Mr. James P. Raskob  
Safety and Regulatory Engineering Manager  
General Electric Co.  
GE Medical Systems Lunar  
726 Heartland Trail  
MADISON WI 53717

Re: K082317  
Trade/Device Name: FRAX\textsuperscript{TM} 10-Year Fracture Risk Software Option for GE Lunar Bone Densitometers  
Regulation Number: 21 CFR 892.1170  
Regulation Name: Bone Densitometer  
Regulatory Class: II  
Product Code: KGI  
Dated: August 12, 2008  
Received: August 13, 2008

Dear Mr. Raskob:

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.

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 Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

- 21 CFR 876.xxx (Gastroenterology/Renal/Urology) 240-276-0115
- 21 CFR 884.xxx (Obstetrics/Gynecology) 240-276-0115
- 21 CFR 894.xxx (Radiology) 240-276-0120
- Other 240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometrics’ (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Premarket Notification
GE Medical Systems Lunar – FRAX™ 10-year Fracture Risk software option

Attachment D

510(k) Indications for Use

510(k) Number (if known): 082317

Device Name: FRAX™ 10-Year Fracture Risk Software Option for GE Lunar Bone Densitometers

The FRAX™ 10-Year Fracture Risk software option is an accessory to currently marketed GE Lunar bone densitometer devices, which are intended to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians.

This software option is intended to provide an assessment of 10-year fracture risk. The option provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the patient’s age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence or absence of several risk factors and is computed using the FRAX™ Fracture Risk Assessment Tool endorsed by the World Health Organization (WHO). The tool has been validated for men and post-menopausal women between 40 and 90 years old. The output is provided in a separate screen display and report that can be viewed or printed or exported to an optional physician report generator tool.

The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the assessment of fracture risk.

Prescription Use XXX AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number 082317