DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 2, 2016

GE Healthcare
(GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC)
% Ms. Nicole Landreville
Regulatory Affairs Program Manager
3030 Ohmeda Drive
MADISON WI 53718

Re: K161682
Trade/Device Name: GE Lunar DXA Bone Densitometers with enCORE version 17
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: KGI
Dated: October 31, 2016
Received: November 1, 2016

Dear Ms. Landreville:

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 below.

510(k) Number *(if known)*
K161682

Device Name
GE Lunar DXA Bone Densitometers with enCORE version 17

Indications for Use *(Describe)*
Optional Atypical Femur Fracture (AFF) software uses Femur images to visualize focal reaction or thickening along the lateral cortex of the femoral shaft which may be accompanied by a transverse radiolucent line. This software provides measurements of the lateral and medial cortex width and quantifies focal thickening of the lateral cortex along the femoral shaft. The beaking index can be displayed and trended across serial scans.

Optional sarcopenia software calculates values based on published definitions and thresholds using measured appendicular lean mass in combination with patient demographics and entered values of muscle strength and physical performance. These values may be useful to health care professionals in their management of sarcopenia.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary

GE Lunar DXA Bone Densitometers with enCORE version 17

510(k) Summary

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

Date:	15-Jun-2016
Submitter:	GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC.) 3030 Ohmeda Drive P.O. Box 7550 Madison, WI, USA 53707
Primary Contact Person:	Nicole Landreville, Eng, RAC Regulatory Affairs Program Manager GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC.) Telephone: (289) 208-2365 Email: Nicole.landreville@ge.com
Secondary Contact Person:	Diane Uriell Regulatory Affairs Director GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC) Telephone: (262) 290-8212 Email: Diane.Uriell@ge.com
Device Trade Name:	***GE Lunar DXA Bone Densitometers with enCORE version 17***
Common/Usual Name:	X-Ray Bone Densitometer
Classification Names: Product Code:	Bone Densitometer (21CFR 892.1170) KGI

Predicate Devices:	1. Lunar DXA Bone Densitometers with enCORE software: • Total Body Composition (k071570 – Product Code: KGI) • RSMI - Relative Skeletal Muscle Index (k113286– Product Code: KGI) • AHA - Advanced Hip Assessment (k072664 – Product Code: KGI) • HAL- Hip Axis Length (k011917 – Product Code: KGI) 2. Hologic Bone Densitometers • Single Energy (SE) Femur Exams (k130277 – Product Code: KGI).
Device Description:	***GE Lunar DXA Bone Densitometers with enCORE version 17*** are composed of a scanner and a computer. The scanner comprises the x-ray source and detector, the patient scan table, the mechanical drive system, and the lowest level portions of the control system. The scanner is in communication with the computer, which is a standard PC. The computer runs the enCORE software, and thus controls the scanner, acquires scan data from the scanner, stores and analyzes the data, and interacts with the human operator. The enCORE software runs on the following list of ***GE Lunar DXA Bone Densitometers :*** • Lunar Prodigy Series: (Prodigy, Prodigy Compact, Prodigy Pro, Prodigy Pro Compact, Prodigy Primo, Prodigy Primo Compact, Prodigy Advance, Prodigy Advance Compact) • Lunar iDXA Series: (iDXA, iDXA Advance, iDXA Pro, iDXA Forma, Lunar iDXA) • DPX Series: DPX-NT & DPX-Bravo. The ***GE Lunar DXA Bone Densitometers with enCORE version 17*** measure the bone mineral density (BMD), lean and fat tissue mass and calculate derivative values of bone mineral content (BMC), area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional/total soft tissue mass ratio, % fat, region % fat, total body % fat, Android % fat, Gynoid % fat, Android/Gynoid ratio (A/G ratio) and Body Mass Index (BMI). The enCORE software is used on GE Lunar DXA bone densitometers. Release 17 of the enCORE software (enCORE 17 or enCORE 17.xx) includes some feature enhancements.

Device Description (Cont.):	GE Lunar DXA Bone Densitometers with enCORE software were modified to include 2 new software features as well as additional cybersecurity enhancements: A- The software will now expand upon its previously cleared Hip Axis Length (k011917) & AHA - Advanced Hip Assessment (k072664) by the addition of an optional feature for Atypical Femur Fracture (AFF): AFFs are stress or insufficiency fractures that occur in the subtrochanteric or diaphyseal regions of the femur and may be associated with long term bisphosphonate use. The new AFF feature brings minor changes to the anatomical sites to extend the DXA femur scan to include the distal femur shaft, measure the lateral and medial cortex width and quantify focal thickening of the lateral cortex along the femoral shaft. The beaking index can be displayed and trended across serial scans. The new AFF indication for use is equivalent to the Hologic Single Energy (SE) Femur Exams (k130277). B- The software will now expand upon its previously cleared Total Body Composition (k071570) and RSMI - Relative Skeletal Muscle Index (k113286) by the addition of an optional feature for Sarcopenia calculation: Sarcopenia is a gradual loss of muscle mass and strength associated with aging and is a factor in the occurrence of frailty, falls, and fractures. Sarcopenia definitions have been published by four leading clinical working groups: • International Working Group on Sarcopenia[1]: • European Working Group on Sarcopenia in Older People[2] • Asian Working Group for Sarcopenia[3] • The Foundation for the National Institutes of Health Biomarkers Consortium Sarcopenia Project[4] All definitions include DXA appendicular lean mass (ALM), a value measured from DXA total body scans, in combination with other measurements of muscle strength and physical performance (e.g. grip strength and gait speed). The new sarcopenia software feature allows the user to select one of the four definitions, extend the total body user interface so user can input muscle strength and physical performance data along with DXA ALM, and compare individual values against clinical thresholds for assessing sarcopenia. The Sarcopenia feature provides a calculated sarcopenia classification using one of the four definitions above. C- The enCORE version 17 software incorporates latest Microsoft security patches and other security enhancements.

Device Description (Cont.):	Sarcopenia references: 1. Fielding RA, Vellas B, Evans WJ, et.al, Sarcopenia: An Undiagnosed Condition in Older Adults. Current Consensus Definition: Prevalence, Etiology, and Consequences. J Am Med Dir Assoc. 2011 May ; 12(4): 249–256. 2. Cruz-Jentoft AJ, Baeyens JP, Bauer JM, et al. Sarcopenia: European consensus on definition and diagnosis: report of the European Working Group on Sarcopenia in Older People. Age Ageing. 2010;39:412–423. 3. Chen LK, Liu LK, Woo J,et.al. Sarcopenia in Asia: consensus report of the Asian Working Group for Sarcopenia. J Am Med Dir Assoc. 2014 Feb;15(2):95-101 4. Studenski SA1, Peters KW, Alley DE,et.al. The FNIH Sarcopenia Project: Rationale, Study Description, Conference Recommendations, and Final Estimates. J Gerontol A Biol Sci Med Sci 2014 May;69(5):547–558
Intended Use:	The intended use of the GE Lunar DXA Bone Densitometers remains the same. The proposed device: "**GE Lunar DXA Bone Densitometers with enCORE version 17 software**" is intended for medical purposes to measure bone density, bone mineral content, and fat and lean tissue content by x-ray transmission measurements through the bone and adjacent tissues.
Indications for Use:	Optional Atypical Femur Fracture (AFF) software uses Femur images to visualize focal reaction or thickening along the lateral cortex of the femoral shaft which may be accompanied by a transverse radiolucent line. This software provides measurements of the lateral and medial cortex width and quantifies focal thickening of the lateral cortex along the femoral shaft. The beaking index can be displayed and trended across serial scans. Optional sarcopenia software calculates values based on published definitions and thresholds using measured appendicular lean mass in combination with patient demographics and entered values of muscle strength and physical performance. These values may be useful to health care professionals in their management of sarcopenia.

Manufacturing Sites:	Site 1: GE Medical Systems Monterrey Mexico, S.A.DE C.V. Calle Espana #300, Parque Industrial Huinala Apodaca, Nuevo Leon, C.P.66645, Mexico Site 2: GE Medical Systems Information Technologies 8200 West Tower Avenue Milwaukee, WI, 53223, USA Site 3: GE MEDICAL SYSTEMS CHINA CO., LTD. no. 19 changjiang road national hi-tech dev. Zone Wuxi, CHINA 214028
Comparison of the technological characteristics:	***GE Lunar DXA Bone Densitometers with enCORE version 17*** employ the same fundamental scientific technology as its predicate devices with the addition of 2 new software features as well as additional cybersecurity enhancements: 1. The optional feature for Atypical Femur Fracture (AFF) brings minor changes to the anatomical sites to extend the DXA femur scan to include the distal femur shaft, measure the lateral and medial cortex width and quantify focal thickening of the lateral cortex along the femoral shaft. The beaking index can be displayed and trended across serial scans. See Table A – AFF Feature Comparison Table with Predicates GE Lunar, Hologic and Proposed device. 2. The optional feature for Sarcopenia provides a calculated sarcopenia classification using one of four definitions published by sarcopenia leading clinical working groups. The physician can compare individual values against clinical thresholds for assessing sarcopenia. See Table B – Sarcopenia Feature Comparison Table with Predicate GE Lunar and Proposed device. 3. The enCORE version 17 software incorporates latest Microsoft security patches and other security enhancements.

Table A – AFF Feature Comparison Table with Predicates GE Lunar, Hologic and Proposed device

Specification	**Predicate Device #1** GE Lunar DXA Bone Densitometers - AHA – Advanced Hip Assessment (k072664) - HAL – Hip Axis Length (k011917)	**Predicate Device #2** Hologic Bone Densitometers - Single Energy (SE) Femur Exams (k130277)	**Proposed** GE Lunar DXA Bone Densitometers with enCORE version 17 - AFF Atypical Femur Fracture	**Discussion of Differences**
Technology	Dual-energy X-ray Absorptiometry (DXA)	Single-energy image	Dual-energy X-ray Absorptiometry (DXA)	Equivalent. enCORE Version 17 AFF image is extending existing GE Lunar DXA femur scans to image distal shaft.
Exam Site	Proximal Femur	Proximal Femur and distal shaft	Proximal Femur and distal shaft	Identical to Hologic (k130277)
Values Displayed	HAL and sub-region lengths, angles, ratios, buckling ratio, section modulus (Z), cortical thickness, cross-sectional area (CSA) and cross-sectional moment of inertia (CSMI).	None	Cortical thickness (beaking index)	Equivalent. enCORE Version 17 AFF feature measures cortical width for larger femoral scan area compared to Advanced Hip Assessment (AHA).
Method of Deformity Assessment	Quantitative	Visual	Visual and Quantitative	Equivalent. enCORE Version 17 combines a visual assessment with quantitative measurements of cortical width.

Table B – Sarcopenia Feature Comparison Table with Predicate GE Lunar and Proposed device

Specification	**Predicate Device #1a** GE Lunar DXA Bone Densitometers - Total Body composition (k071570)	**Predicate Device #1b** GE Lunar DXA Bone Densitometers - RSMI Relative Skeletal Muscle Index (k113286)	**Proposed** GE Lunar DXA Bone Densitometers with enCORE version 17 - Sarcopenia calculator	**Discussion of Differences**
Technology	Dual-energy X-ray Absorptiometry (DXA)	Dual-energy X-ray Absorptiometry (DXA)	Dual-energy X-ray Absorptiometry (DXA)	Identical
Anatomical Sites	Regional and Whole Body	Regional and Whole Body	Regional and Whole Body	Identical
Values Displayed	• Bone Mineral Density (BMD) • Lean and Fat Tissue mass • Bone Mineral Content (BMC) • Area • Soft Tissue Mass • Regional Soft Tissue Mass • Total Soft Tissue Mass • Fat Free Mass • Regional/Total Soft Tissue Mass Ratios • %Fat • Region %fat • Total Body %fat	• Bone Mineral Density (BMD) • Lean and Fat Tissue mass • Bone Mineral Content (BMC) • Area • Soft Tissue Mass • Regional Soft Tissue Mass • Total Soft Tissue Mass • Fat Free Mass • Regional/Total Soft Tissue Mass Ratios • %Fat • Region %fat • Total Body %fat • RSMI – Relative Skeletal Muscle Index	• Bone Mineral Density (BMD) • Lean and Fat Tissue mass • Bone Mineral Content (BMC) • Area • Soft Tissue Mass • Regional Soft Tissue Mass • Total Soft Tissue Mass • Fat Free Mass • Regional/Total Soft Tissue Mass Ratios • %Fat • Region %fat • Total Body %fat • RSMI – Relative Skeletal Muscle Index • **FNIH - Foundation for the National Institutes of Health Sarcopenia Project:** • **AWGS - Asian Working Group for Sarcopenia** • **EWGSOP - European Working Group on Sarcopenia in Older People** • **IWGS - International Working Group on Sarcopenia**	Equivalent. The Total Body composition measurements for lean mass for arms and legs (k071570) were used to calculate Relative Skeletal Muscle Index (k113286). enCORE Version 17 now calculates four similar values based on newly published definitions.

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The ***GE Lunar DXA Bone Densitometers with enCORE version 17*** and its applications comply with voluntary standards. 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) ▪ Simulated use testing (Validation) There is no change to the system hardware. Although these changes do not impact the intended use of the system, adding the AFF and Sarcopenia calculator optional software features added two new Indications for Use. These software changes were tested successfully and as described in supporting evidence: • Summary of the verification and validation testing performed on the enCORE software version 17. Test results confirmed that the design outputs met the design input requirements. • Summary of the non-clinical evaluation of the "AFF" software option and the non-clinical evaluation of the optional sarcopenia calculator software. These bench testing results confirmed the substantial equivalence in terms of safety and effectiveness to the predicate devices. There is no change to the diseases or conditions expected to be diagnosed, treated, prevented, cured or mitigated. There is no change to the patient population.

Determination of Substantial Equivalence: (Cont.)	Summary of Clinical Tests: The subject of this premarket submission, ***GE Lunar DXA Bone Densitometers with enCORE version 17***, did not require clinical studies to support substantial equivalence. A clinical literature search was performed and provided to support the additional optional software features calculations and associated indications for use.
Conclusion:	The ***GE Lunar DXA Bone Densitometers with enCORE version 17*** expands its previously cleared features and indications for use but does not result in any new potential safety risks. The ***GE Lunar DXA Bone Densitometers with enCORE version 17*** have the same technological characteristics, and performs as well as the predicate devices currently on the market. Based on the information supplied in this submission, it is the conclusion of GE Healthcare that the ***GE Lunar DXA Bone Densitometers with enCORE version 17*** is substantially equivalent to other marketed devices with similar indications for use and meeting the same standards.