GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
% Nicole Landreville, Eng, RAC, FRAPS
Regulatory Affairs Manager
3030 Ohmeda Drive
MADISON WI 53718

April 20, 2018

Re: K180782
Trade/Device Name: Aria
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: KGI
Dated: March 21, 2018
Received: March 26, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180782

Device Name
Aria

Indications for Use *(Describe)*

X-ray Bone Densitometer designed to estimate the bone mineral density of patients when medically indicated by their physicians.

- Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, Forearm). These values can then be compared to an adult reference population at the sole discretion of the physician.
- Provides an assessment of relative fracture risk based on the patient's T-score value using the categories of fracture risk defined by the World Health Organization (WHO).
- Provides an assessment of 10-year fracture risk using WHO FRAX model.
- Provides a standardized bone density report using data from the densitometer and physician-generated assessments

based on the patient's demographics, which can assist the physician in communicating scan results to the patient and the patient's referring physician.

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

Aria

510(k) Summary

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

Date Submitted:	21-Mar-2018
Submitter:	GE Healthcare GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC. 3030 Ohmeda Drive Madison, WI, USA 53707
Primary Contact Person:	Nicole Landreville, Eng, RAC, FRAPS Regulatory Affairs 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 Telephone: (262) 290-8212 Email: Diane.Uriell@ge.com
Device Trade Name:	Aria
Common/Usual Name:	X-Ray Bone Densitometer
Classification Names: Product Code:	Regulation Name: Bone Densitometer Regulation: 21 CFR 892.1170 Classification: Class II Product Codes: KGI

Predicate Device:	Prodigy (K982267 and K161682) Regulation Name: Bone Densitometer Regulation: 21 CFR 892.1170 Classification: Class II Product Codes: KGI
Device Description:	The Aria X-ray Bone Densitometer is designed to be a value product version of the predicate device, the Prodigy (K982267 and K161682). Like its predicate Prodigy device, the proposed Aria device is composed of a scanner and a computer that runs the software. 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. Aria X-ray Bone Densitometer functions with the same software as the one that is FDA cleared under GE Lunar DXA Bone Densitometers with enCORE version 17 (K161682).
Intended Use:	The bone densitometer is designed to estimate the bone mineral density of patients when medically indicated by their physicians.
Indications for Use:	X-ray Bone Densitometer designed to estimate the bone mineral density of patients when medically indicated by their physicians. • Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, Forearm). These values can then be compared to an adult reference population at the sole discretion of the physician. • Provides an assessment of relative fracture risk based on the patient's T-score value using the categories of fracture risk defined by the World Health Organization (WHO). • Provides an assessment of 10-year fracture risk using WHO FRAX model. • Provides a standardized bone density report using data from the densitometer and physician-generated assessments based on the patient's demographics, which can assist the physician in communicating scan results to the patient and the patient's referring physician.

Technology:	Aria employs the same fundamental scientific technology, the same mechanism of action and working principle as the predicate device Prodigy (K982267). The proposed device and the predicate device have the same structural composition with minor differences. They are both composed of 3 main components: 1. Scanner: a. Scanner Table: The proposed device and the predicate device share a similar design architecture and similar manufacturing processes. The scanners differ slightly in physical sizes (when comparing the Prodigy compact with Aria scanner). Both support the same maximum patient weight. b. Detector: Identical sensor type with different number of elements. c. X-Ray generator: Identical tube voltage and K-edge filter with different max current output. 2. Computer: The same computer model is used for Aria and its predicate device. 3. Software : The proposed device and the predicate device are controlled by the same enCORE software (K161682). Some high-end features are not activated when installed on an Aria system (ex.: features related with body composition and metabolic health). Aria's intended use is a sub-set of Prodigy's intended use in that it provides an estimate of the bone mineral density. Aria's indications for use are a sub-set of the predicate Prodigy device indications for use. The additional IFUs on Prodigy relate with metabolic health and advanced BMD features do not apply to the proposed device. These differences do not significantly affect safety and/or effectiveness.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The Aria X-ray Bone Densitometer and its applications comply with voluntary standards. • ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; • IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests;

Determination of Substantial Equivalence: (Cont.)	• IEC 60601-2-28 Medical Electrical Equipment - Part 2-28: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Tube Assemblies For Medical Diagnosis; • IEC 60601-1-3 Medical Elec. Equipment – Part 1-3: General Requirements for Safety. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment; • IEC 60601-1-8 Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems; • IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability; • IEC 62366 Medical devices - Application of usability engineering to medical Devices; • AAMI / ANSI / ISO 10993-1 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process; • AAMI / ANSI / ISO 10993-5 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity; • AAMI / ANSI / IEC 62304 Medical Device Software - Software Life Cycle Processes; • ISO 14971 - Medical Devices - Application Of Risk Management To Medical Devices; • ISO 15223-1 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements; • PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) set. (Radiology); 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 ▪ Performance testing (Verification) ▪ Safety testing (Verification) ▪ Simulated use testing (Validation)

Determination of Substantial Equivalence: (Cont.)	Risks were reviewed and mitigated with design controls and labeling. The mitigations were verified and validated as a part of the design verification and validation testing that has been executed with acceptable results. The testing/documentation we provided for Aria were completed according to the following FDA guidance documents: • Usability: Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On: February 3, 2016. • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005. • Guidance for Off-the-Shelf Software Use in Medical Devices, September 1999. • General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002. • Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the Shelf (OTS) Software, January 2005. • Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued on October 2, 2014. • FDA Guidance on Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices issued on July 11, 2016. In addition, Aria X-Ray bone densitometer was designed to meet the applicable federal performance standards listed within 21 CFR Subchapter J as follows: • 21 CFR 1010 – Performance Standards for Electronic Products: General • 21 CFR 1020.30 – Diagnostic X-Ray Systems and Their Major Components • 21 CFR 1040.10 – Laser Products <u>Summary of Clinical Tests:</u> The proposed Aria device intended use / indications for use are a subset of the predicate Prodigy device intended use / indications for use. The subject of this premarket submission, Aria, did not require clinical studies to support substantial equivalence.

Determination of Substantial Equivalence: (Cont.)	<u>Bench Testing: Precision and Accuracy</u> During product development, precision and accuracy tests are performed over a wide range of phantoms to cover the variation in human subjects. Repeat measurements on a phantom are performed to verify precision using standard statistical analysis of the data. Similarly, a set of phantoms with different BMD and tissue composition properties is measured to verify accuracy by showing an excellent correlation to previously released Prodigy product. The method used consist of verifying BMD precision and accuracy for various scan sites by measuring phantom set and calculate mean, standard deviation, %CV, and correlation to expected values to ensure clinical performance requirements are met. The acceptance criteria used are as follows for all sites (AP Spine BMD, Femur BMD and Forearm BMD): • Precision <=1.0% • Accuracy r>0.95 The results of the bench testing provided in the submission demonstrate that Aria can accurately and precisely estimate bone density. Design verification and validation testing was performed to confirm that the safety and effectiveness of the device has not been affected. The test plans and results have been executed with acceptable results.
Conclusion:	The proposed Aria device intended use / indications for use are a subset of the predicate Prodigy device intended use / indications for use. The differences in the hardware do not result in any new potential safety risks. Aria has the same technological characteristics, and performs as well as the predicate Prodigy device currently legally marketed on the US market. After analyzing design verification and validation testing it is the conclusion of GE Healthcare that Aria is as safe, as effective, and its performance is substantially equivalent to the predicate Prodigy device.