April 20, 2026

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
% Christopher Paulik
Senior Manager, Regulatory Affairs
3030 Ohmeda Drive
MADISON, WI 53718

Re: K252718
Trade/Device Name: Lunar Astra
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: Class II
Product Code: KGI
Dated: March 12, 2026
Received: March 12, 2026

Dear Christopher Paulik:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

GABRIELA M. RODAL -S Digitally signed by GABRIELA M. RODAL -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252718

Device Name
Lunar Astra

Indications for Use *(Describe)*
The x-ray bone densitometer supports the following indications for use:

A) Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, Total Body, and Forearm). These values can then be compared to an adult reference population at the sole discretion of the physician.

B) 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).

C) Provides an assessment of 10-year fracture risk using WHO FRAX model.

D) 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.

E) Optional Hand BMD software estimates the BMD at the hand.

F) Optional Vertebral Assessment Suite software provides an x-ray image of the spine for qualitative visual assessment in order to identify vertebral deformations and estimate vertebral heights (morphometry).

G) Optional Orthopedic software estimates periprosthetic BMD of an orthopedic hip or knee implant (pre- and post-surgery).

H) Optional Birth to 20 software measures bone mineral content (BMC), bone mineral density (BMD) and body composition (lean body mass and fat mass) in patients from birth to 20 years of age. The software provides a comparison of measured variables obtained by dual energy x-ray absorptiometry to a database of reference values for patients 5-19 years of age. These data can be used for comparative purposes at the sole discretion of the physician. The software does not provide a reference population for comparative purposes for patients younger than 5 years of age.

I) Optional Body Composition software measures the regional and whole body bone mineral density (BMD), lean and fat tissue mass, and calculates other derivative values which can be displayed in user-defined statistical formats and trends, and compared to reference populations at the sole discretion of the healthcare professional. Some of the diseases/ conditions for which body composition values are useful include chronic renal failure, anorexia nervosa, obesity, AIDS/ HIV, and cystic fibrosis.

J) The MirrorImage function used on the GE HealthCare Lunar DXA bone densitometers can be used to estimate the total body composition and bone mineral density (BMD) when regions of the body are outside of the scan window by using scanned data from the corresponding region(s) on the opposite half of the body.

K) Optional CoreScan software estimates the Visceral Adipose Tissue (VAT) content and the Subcutaneous Adipose Tissue (SAT) content within the android region in a male or female population between the ages of 18 and 90 with a BMI between 18.5 and 40, excluding pregnant women. The content that is estimated is the VAT Mass, VAT Volume, VAT Area, SAT Mass, SAT Volume, and SAT Area. The values can be displayed in user-defined statistical formats and trends. Some of the diseases/conditions for which VAT estimation can be useful include hypertension, impaired fasting glucose,

impaired glucose tolerance, diabetes mellitus, dyslipidemia, metabolic syndrome, and some cancers that are correlated to adipose tissue inflammation.

L) Optional total body composition software estimates the Resting Metabolic Rate (RMR) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends.

M) Optional total body composition software estimates the Relative Skeletal Muscle Index (RSMI) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends.

N) Optional Advanced Hip Assessment (AHA) software provides a measurement of hip axis length (HAL) and a mean value of HAL for Caucasian and Asian females on femur images. It also calculates hip geometry values used to evaluate the structural properties of the hip.

O) 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.

P) 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.

Q) Optional Neck to Knee software feature provides a complete bone and body composition assessment in one optimized exam including BMD, Fracture Risk, Adiposity/Metabolic status, and Sarcopenia status.

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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510(k) Summary:

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

Date:	April 20, 2026
Owner/Submitter:	GE Medical Systems Ultrasound & Primary Care Diagnostics LLC 3030 Ohmeda Dr, Madison, WI 53718, United States
Primary Contact Person:	Christopher Paulik Senior Regulatory Affairs Manager Email: Christopher.A.Paulik@gehealthcare.com Contact Phone Number: +1 (262) 8945415
Secondary Contact Person:	Gregory Pessato Regulatory Affairs Director Email: Gregory.pessato@gehealthcare.com Contact Phone Number: +33130704040
Device Trade Name:	Lunar Astra
Common/Usual Name:	Bone densitometer
Regulation Name:	Bone densitometer
Regulation:	21 CFR 892.1170
Classification:	Class II
Product Code:	KGI
Predicate Device:	Lunar iDXA (K052581) 21 CFR 892.1170 (KGI) Class II
Secondary Predicate Device:	GEHC DXA Bone Densitometer with enCORE version 18 (K191112) 21 CFR 892.1170 (KGI) Class II
Manufacturing site:	GE Hualun Medical Systems Co., Ltd. No. 1, Yong Chang North Road, Beijing Economic Technological Development Zone, 100176 Beijing, P.R. China
Device Description:	The Lunar Astra with Lunar Software v1.0 is intended to measure bone mineral density and body composition (lean and fat tissue mass) when medically indicated by a licensed healthcare professional. It can be used to perform BMD (Bone Mineral Density) measurements of the spine, femur, forearm, hand, orthopedic hip and knee, total body, body composition measurements of regional and whole body, as well as imaging applications for lateral spine vertebral deformation assessment and atypical femur fracture assessment. Applications can be performed with the patient lying in the supine (spine, femur, forearm, hand, orthopedic hip and knee, total body) or decubitus (lateral spine) position or sitting next to the system (forearm and hand). The intended users are medical professionals with knowledge and experience required to work with x-ray equipment.
Technology:	The proposed Lunar Astra with Lunar Software v1.0 uses the same fundamental technology and principles of operation as the predicates Lunar iDXA (K052581) and

	enCORE version 18 (K191112). A technique called dual-energy X-ray absorptiometry (DXA) is used to measure the attenuation of x-rays of two different energy levels after they pass through the body of a subject. As bone, fat tissue, and lean tissue absorb the different energy x-rays at different rates, the relative attenuation of each x-ray energy is measured (referred to as count rates) and used to calculate the composition of each pixel. The primary components of Lunar Astra with Lunar Software v1.0 remain the same as the predicate device: (1) an x-ray source (2) an x-ray detector (3) a support / table for holding the subject between source and detector (4) a mechanical means to move the source and detector (5) software and electronic controls for the previously mentioned components. The user operates the Lunar Astra from a PC workstation loaded with the Lunar Software v1.0 on a Windows operating system. The user inputs the patient information directly, from a database stored in the software, or via a hospital information system (HIS). The prescribed area is then scanned to acquire the data used to compute the bone mineral density, lean and fat tissue mass for the study. The results of the study can then be viewed on the computer display, printed, and/or transmitted via network to PACS or EMR for archival. The basic acquisition and scan modes (modes of operation) as well as computer algorithms (formulae and techniques) used to compute bone mineral density, lean and fat tissue mass retain the same function and characteristics as used on the predicate device.

Indications for Use:	The x-ray bone densitometer supports the following indications for use: A) Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, Total Body, and Forearm). These values can then be compared to an adult reference population at the sole discretion of the physician. B) 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). C) Provides an assessment of 10-year fracture risk using WHO FRAX model. D) 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. E) Optional Hand BMD software estimates the BMD at the hand. F) Optional Vertebral Assessment Suite software provides an x-ray image of the spine for qualitative visual assessment in order to identify vertebral deformations and estimate vertebral heights (morphometry). G) Optional Orthopedic software estimates periprosthetic BMD of an orthopedic hip or knee implant (pre- and post-surgery). H) Optional Birth to 20 software measures bone mineral content (BMC), bone mineral density (BMD) and body composition (lean body mass and fat mass) in patients from birth to 20 years of age. The software provides a comparison of measured variables obtained by dual energy x-ray absorptiometry to a database of reference values for patients 5-19 years of age. These data can be used for comparative purposes at the sole discretion of the physician. The software does not provide a reference population for comparative purposes for patients younger than 5 years of age. I) Optional Body Composition software measures the regional and whole body bone mineral density (BMD), lean and fat tissue mass, and calculates other derivative values which can be displayed in user- defined statistical formats and trends, and compared to reference populations at the sole discretion of the healthcare professional. Some of the diseases/conditions for which body composition values are useful include chronic renal failure, anorexia nervosa, obesity, AIDS/HIV, and cystic fibrosis. J) The MirrorImage function used on the GE HealthCare Lunar DXA bone densitometers can be used to estimate the total body composition and bone mineral density (BMD) when regions of the body are outside of the scan window by using scanned data from the corresponding region(s) on the opposite half of the body.

	K) Optional CoreScan software estimates the Visceral Adipose Tissue (VAT) content and the Subcutaneous Adipose Tissue (SAT) content within the android region in a male or female population between the ages of 18 and 90 with a BMI between 18.5 and 40, excluding pregnant women. The content that is estimated is the VAT Mass, VAT Volume, VAT Area, SAT Mass, SAT Volume, and SAT Area. The values can be displayed in user-defined statistical formats and trends. Some of the diseases/ conditions for which VAT estimation can be useful include hypertension, impaired fasting glucose, impaired glucose tolerance, diabetes mellitus, dyslipidemia, metabolic syndrome, and some cancers that are correlated to adipose tissue inflammation. L) Optional total body composition software estimates the Resting Metabolic Rate (RMR) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends. M) Optional total body composition software estimates the Relative Skeletal Muscle Index (RSMI) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends. N) Optional Advanced Hip Assessment (AHA) software provides a measurement of hip axis length (HAL) and a mean value of HAL for Caucasian and Asian females on femur images. It also calculates hip geometry values used to evaluate the structural properties of the hip. O) 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. P) 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. Q) Optional Neck to Knee software feature provides a complete bone and body composition assessment in one optimized exam including BMD, Fracture Risk, Adiposity/Metabolic status, and Sarcopenia status.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE:

High- level comparison between predicate and subject device is provided below in Table 1.

Table 1: High-level Comparison of Subject Device to Predicate

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
Intended Use	The bone densitometer is designed to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians.	The bone densitometer is designed to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians.	The bone densitometer is designed to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by a licensed healthcare professional.	Same as both Predicates Intended use for Lunar Astra with Lunar Software v1.0 is clarified from "physician" to "by a licensed healthcare professional".
Indications for Use (IFU)	The Lunar iDXA Bone Densitometer provides an estimate of bone mineral density and fat and lean tissue mass. The values can then be compared to a reference population at the sole discretion of the physician.	The x-ray bone densitometer supports the following indications for use:	The x-ray bone densitometer supports the following indications for use:	The subject device's IFU is broader but contains the primary predicate's IFU and is similar to the secondary predicate's IFU. Refer to the rows below.
IFU A)	N/A	Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, Total Body, and Forearm). These values can then be compared to an adult reference population at the sole discretion of the physician.	Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, Total Body, and Forearm). These values can then be compared to an adult reference population at the sole discretion of the physician.	Identical to Secondary Predicate
IFU B)	N/A	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 relative fracture risk based on the patient's T-score value using the categories of fracture risk defined by the World Health Organization (WHO).	Identical to Secondary Predicate
IFU C)	N/A	Provides an assessment of 10-year fracture risk using WHO FRAX model.	Provides an assessment of 10-year fracture risk using WHO FRAX model.	Identical to Secondary Predicate
IFU D)	N/A	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.	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.	Identical to Secondary Predicate

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
IFU E)	N/A	Optional Hand BMD software estimates the BMD at the hand.	Optional Hand BMD software estimates the BMD at the hand.	Identical to Secondary Predicate
IFU F)	N/A	Optional Dual-Energy Vertebral Assessment software provides an x-ray image of the spine for qualitative visual assessment in order to identify vertebral deformations and estimate vertebral heights (morphometry)	Optional Vertebral Assessment Suite software provides an x-ray image of the spine for qualitative visual assessment in order to identify vertebral deformations and estimate vertebral heights (morphometry)	Identical to Secondary Predicate "Dual-Energy Vertebral Assessment" is rebranded as "Vertebral Assessment Suite". No change in functionality
IFU G)	N/A	Optional Orthopedic software estimates periprosthetic BMD of an orthopedic hip or knee implant (pre- and post-surgery).	Optional Orthopedic software estimates periprosthetic BMD of an orthopedic hip or knee implant (pre- and post-surgery).	Identical to Secondary Predicate
IFU H)	N/A	Optional Complete Pediatric software option measures bone mineral content (BMC), bone mineral density (BMD) and body composition (lean body mass and fat mass) in patients from birth to 20 years of age. The software provides a comparison of measured variables obtained by dual energy x-ray absorptiometry to a database of reference values for patients 5-19 years of age. These data can be used for comparative purposes at the sole discretion of the physician. The software does not provide a reference population for comparative purposes for patients younger than 5 years of age.	Optional Birth to 20 software measures bone mineral content (BMC), bone mineral density (BMD) and body composition (lean body mass and fat mass) in patients from birth to 20 years of age. The software provides a comparison of measured variables obtained by dual energy x-ray absorptiometry to a database of reference values for patients 5-19 years of age. These data can be used for comparative purposes at the sole discretion of the physician. The software does not provide a reference population for comparative purposes for patients younger than 5 years of age.	Identical to Secondary Predicate "Complete Pediatric" is rebranded as "Birth to 20". No change in functionality
IFU I)	N/A	Optional Body Composition software measures the regional and whole body bone mineral density (BMD), lean and fat tissue mass, and calculates other derivative values which can be displayed in user-defined statistical formats and trends and compared to reference	Optional Body Composition software measures the regional and whole body bone mineral density (BMD), lean and fat tissue mass, and calculates other derivative values which can be displayed in user-defined statistical formats and trends and compared to reference	Identical to Secondary Predicate

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
		populations at the sole discretion of the healthcare professional. Some of the diseases/conditions for which body composition values are useful include chronic renal failure, anorexia nervosa, obesity, AIDS/HIV, and cystic fibrosis.	populations at the sole discretion of the healthcare professional. Some of the diseases/conditions for which body composition values are useful include chronic renal failure, anorexia nervosa, obesity, AIDS/HIV, and cystic fibrosis.	
IFU J)	N/A	The MirrorImage function used on the GE Lunar DXA bone densitometers can be used to estimate the total body composition and bone mineral density (BMD) when regions of the body are outside of the scan window by using scanned data from the corresponding region(s) on the opposite half of the body.	The MirrorImage function used on the GE Lunar DXA bone densitometers can be used to estimate the total body composition and bone mineral density (BMD) when regions of the body are outside of the scan window by using scanned data from the corresponding region(s) on the opposite half of the body.	Identical to Secondary Predicate
IFU K)	N/A	Optional CoreScan software estimates the Visceral Adipose Tissue (VAT) content and the Subcutaneous Adipose Tissue (SAT) content within the android region in a male or female population between the ages of 18 and 90 with a BMI between 18.5 and 40, excluding pregnant women. The content that is estimated is the VAT Mass, VAT Volume, VAT Area, SAT Mass, SAT Volume, and SAT Area. The values can be displayed in user-defined statistical formats and trends. Some of the diseases/conditions for which VAT estimation can be useful include hypertension, impaired fasting glucose, impaired glucose tolerance, diabetes mellitus, dyslipidemia, metabolic syndrome, and some cancers that are correlated to adipose tissue inflammation.	Optional CoreScan software estimates the Visceral Adipose Tissue (VAT) content and the Subcutaneous Adipose Tissue (SAT) content within the android region in a male or female population between the ages of 18 and 90 with a BMI between 18.5 and 40, excluding pregnant women. The content that is estimated is the VAT Mass, VAT Volume, VAT Area, SAT Mass, SAT Volume, and SAT Area. The values can be displayed in user-defined statistical formats and trends. Some of the diseases/conditions for which VAT estimation can be useful include hypertension, impaired fasting glucose, impaired glucose tolerance, diabetes mellitus, dyslipidemia, metabolic syndrome, and some cancers that are correlated to adipose tissue inflammation.	Identical to Secondary Predicate

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
IFU L)	N/A	Optional total body composition software estimates the Resting Metabolic Rate (RMR) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends.	Optional total body composition software estimates the Resting Metabolic Rate (RMR) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends.	Identical to Secondary Predicate
IFU M)	N/A	Optional total body composition software estimates the Relative Skeletal Muscle Index (RSMI) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends	Optional total body composition software estimates the Relative Skeletal Muscle Index (RSMI) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends	Identical to Secondary Predicate
IFU N)	N/A	Optional Advanced Hip Assessment (AHA) software provides a measurement of hip axis length (HAL) and a mean value of HAL for Caucasian and Asian females on femur images. It also calculates hip geometry values used to evaluate the structural properties of the hip.	Optional Advanced Hip Assessment (AHA) software provides a measurement of hip axis length (HAL) and a mean value of HAL for Caucasian and Asian females on femur images. It also calculates hip geometry values used to evaluate the structural properties of the hip.	Identical to Secondary Predicate
IFU O)	N/A	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 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.	Identical to Secondary Predicate
IFU P)	N/A	Optional sarcopenia software calculates values based on published definitions and thresholds using measured	Optional sarcopenia software calculates values based on published definitions and thresholds using measured	Identical to Secondary Predicate

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
		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.	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	
IFU Q)	N/A	Optional DXAVision software feature provides a complete bone and body composition assessment in one optimized exam including BMD with TBS, Fracture Risk, Adiposity/Metabolic status, and Sarcopenia status.	Optional Neck-to-Knee software feature provides a complete bone and body composition assessment in one optimized exam including BMD, Fracture Risk, Adiposity/Metabolic status, and Sarcopenia status.	Identical to Secondary Predicate "DXAVision" is rebranded as "Neck-to-Knee". No change in functionality
IFU R)	N/A	TBS iNsight is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the antero-posterior spine DXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age-matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture. TBS iNsight provides as an option an assessment of 10-year fracture risk. It 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 WHO's FRAX® Fracture Risk Assessment Tool, after adjustment for the TBS. The tool has been validated for Caucasian and Asian men and post-menopausal women between 40 and 90 years old. TBS provides information independent of	N/A	Removed from Secondary Predicate The Trabecular Bone Score (TBS) software option (cleared in K152299) is now distributed as standalone software that is provided by the original equipment manufacturer (OEM) Medimaps. This required GEHC to remove this option as embedded within the Lunar Software v1.0, which is a change to how TBS was distributed in the secondary predicate device enCORE version 18. No change in functionality.

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
		BMD value; it is used as a complement to the data obtained from the DXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers…). The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk. The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time. Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software does not diagnose disease or recommend treatment regimens. Only the health care professional can make these judgments.		
Contraindications	No contraindications	No contraindications	No contraindications	Identical to both Predicates
Environment of use	Prescription only	Prescription only	Prescription only	Identical to both Predicates
Intended Users	Medical professionals with knowledge and experience required to work with x-ray equipment. Prescription use only.	Medical professionals with knowledge and experience required to work with x-ray equipment. Prescription use only.	Medical professionals with knowledge and experience required to work with x-ray equipment. Prescription use only.	Identical to both Predicates
Patient Population	Intended patient population is pediatrics (age 0-19), adults, and elderly (over 65 years old).	Intended patient population is pediatrics (age 0-19), adults, and elderly (over 65 years old).	Intended patient population is pediatrics (age 0-19), adults, and elderly (over 65 years old).	Identical to both Predicates

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
X-Ray Tube Assembly	100kV/2.5mA monoblock Insert: Lohmann X-ray GmbH 110/3 EFK K-edge filter: Samarium	N/A- Not a software component, comparison is done with the primary predicate device Lunar iDXA (K052581)	76kV/3.5mA monoblock Insert: Wansen 105739-170 K-edge filter: Cerium	Changed from Primary Predicate Lunar Astra tube uses a different tube insert with lower kV and higher mA. K-edge filter material is changed to provide optimal energy separation for the kV used. The Lunar Astra X-ray source reaches the needed energy level quickly, so it does not need a mechanical shutter to start or stop the X-ray exposure.
Effective Energy (KeV)	40 KeV Low Energy Peak/72 KeV High Energy Peak	N/A- Not a software component, comparison is done with the primary predicate device Lunar iDXA (K052581)	37 KeV Low Energy Peak/59 KeV High Energy Peak	Changed from Primary Predicate The decrease in KeV is due to lowering the X-ray tube voltage from 100 kV to 76 kV. This change does not affect functionality, because the system automatically adjusts for the difference in X-ray signals. It uses these adjusted values to calculate fat fraction, tissue thickness, bone mineral density, etc.
Detector	Material CdTe Detector pitch of 2.5 x 0.8 mm Image resolution: 1.2- 1.6lp/mm (depending on direction)	N/A- Not a software component, comparison is done with the primary predicate device Lunar iDXA (K052581)	Material CdTe Detector pitch of 1.2 x 1.2 mm Image resolution: 1.2-1.3lp/mm (depending on direction)	Changed from Primary Predicate The Lunar Astra detector uses same material (CdTe) and technology (photon counting). The image pixel size was adjusted for tube power and distance between the X-ray source and the image detector differences to maintain the same BMD precision as the predicate.
Collimator	Narrow-angle fan beam with Shutter	N/A-Not a software component, comparison is done with the primary predicate device Lunar iDXA (K052581)	Narrow-angle fan beam, No shutter, beam collimation only	Changed from Primary Predicate The Lunar Astra does not provide a shutter to initiate / terminate an acquisition (refer to "X-Ray Tube Assembly" change in this table)
Scanner Table	1) Max scan window (WxL): 66x198 cm 2) Max patient weight: 500 lbs	N/A- Not a software component, comparison is done with the primary predicate device Lunar iDXA (K052581)	1) Max scan window (WxL): 67x198 cm 2) Max patient weight: 525 lbs 3) Table pad: Polyethylene foam with	Changed from Primary Predicate The Lunar Astra scanner table supports heavier patients, has a wider transverse

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
	3) Table pad: Urethane-coated fabric material over foam core. Imprinted scan window outline		Polyurethane outer skin. Raised scan window outline	scan window range, and an updated table pad.
Scan Arm Control Panel	Push button and indicator lights. Emergency stop, Positioning buttons, Start scan button	N/A- Not a software component, comparison is done with the primary predicate device Lunar iDXA (K052581)	Push button and indicator lights. Emergency stop, Positioning buttons, Start scan button, Home and Stop buttons	Changed from Primary Predicate Lunar Astra adds Home and Stop buttons to the control panel to allow the operator to perform these functions at the device in addition to the workstation.
Quality Assurance (QA) Block	External	N/A- Not a software component, comparison is done with the primary predicate device Lunar iDXA (K052581)	Internal	Changed from Primary Predicate Lunar Astra daily QA block is now built into the table in a fixed position where QA is performed. The internal QA block provides the same function but is internal to the system.
Exposure Time (Standard mode)	- AP Spine: 30 sec - Femur: 30 sec - Total Body: 339 sec	- AP Spine: 30 sec - Femur: 30 sec - Total Body: 339 sec	- AP Spine: 28 sec - Femur: 28 sec - Total Body: 225 sec	Changed from Primary Predicate Lunar Astra Total Body scans use a faster speed, resulting in a lower exposure time. Scan speeds for spine and femur are similar.
Skin Entrance Dose (Standard mode)	- AP Spine: 146 µGy - Femur: 146 µGy - Total Body: 3 µGy	- AP Spine: 146 µGy - Femur: 146 µGy - Total Body: 3 µGy	- AP Spine: 72 µGy - Femur: 72 µGy - Total Body: 3 µGy	Changed from Primary Predicate Lunar Astra scans are lower dose compared to Lunar iDXA due to lower kV tube but are able to achieve the same performance.
Precision	- AP Spine L1-L4/L2-L4 BMD: 1.0% (0.010 g/cm2) - Femur Total BMD: 1.0% (0.010 g/cm2) - Total Body Total BMD: 1.0% (0.010 g/cm2) - Precision for other sites will range 1-3%.	- AP Spine L1-L4/L2-L4 BMD: 1.0% (0.010 g/cm2) - Femur Total BMD: 1.0% (0.010 g/cm2) - Total Body Total BMD: 1.0% (0.010 g/cm2) - Precision for other sites will range 1-3%.	- AP Spine L1-L4/L2-L4 BMD: 1.0% (0.010 g/cm2) - Femur Total BMD: 1.0% (0.010 g/cm2) - Total Body Total BMD: 1.0% (0.010 g/cm2) - Precision for other sites will range 1-3%.	Identical to both Predicates

Specification	Primary Predicate Device Lunar iDXA (K052581)	Secondary predicate device enCORE version 18 (K191112)	Proposed Device Lunar Astra with Lunar Software v1.0	Discussion of differences between Proposed device and Predicate device
Accuracy	Within 0.030 g/cm2 of its expected value which ensures the linear correlation for BMD (R ≥ 0.99)	Within 0.030 g/cm2 of its expected value which ensures the linear correlation for BMD (R ≥ 0.99)	Within 0.030 g/cm2 of its expected value which ensures the linear correlation for BMD (R ≥ 0.99)	Identical
Algorithm	N/A- Software, comparison is done with the secondary predicate device enCORE version 18 (K191112)	Calibration, daily QA, acquisition and analysis algorithms.	Calibration, daily QA, acquisition and analysis algorithms.	Changed from Secondary Predicate Basic acquisition, scan modes and computer algorithms used to compute bone mineral density, lean and fat tissue mass retain the same function and characteristics as their current usage. The updates were due to the introduction of the Lunar Astra hardware.
eDelivery	N/A- Software, comparison is done with the secondary predicate device enCORE version 18 (K191112)	Not available	Available	Changed from Secondary Predicate Lunar Software v1.0 allows the software to be delivered remotely over the internet (called e-Delivery), instead of using a DVD or USB like the current enCORE version 18. No change to installation package, only delivery way is different.

PERFORMANCE DATA: Determination of Substantial Equivalence

Summary of Non-Clinical Tests:
The following quality assurance measures were applied to the development of Lunar Astra with Lunar Software v1.0:

1. Risk Analysis
2. Requirements Reviews
3. Design Reviews
4. Testing on unit level (Module verification)
5. Integration testing (System verification)
6. Performance testing (Verification)
7. Safety testing (Verification)
8. Simulated use testing (Validation)

The precision and accuracy testing was performed using multiple anthropomorphic phantoms representing clinical sites across adult, pediatric, and infant anatomies. Lunar Astra with Lunar Software v1.0 was evaluated for BMD, BMC, and body composition metrics, with results compared to predefined specifications and predicate device. Additional bench tests assessed image resolution and verified software features. All tests met acceptance criteria, demonstrating substantial equivalence in safety and effectiveness.

The Lunar Astra with Lunar Software v1.0 verification and validation testing was performed to confirm that the safety and effectiveness of the device have not been affected. The test plans and results have been executed with acceptable results. Conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.

Summary of Clinical testing:
Clinical images were provided for the evaluation of the LunarVision feature.

CONCLUSION:

The design verification and validation testing and bench testing demonstrated that Lunar Astra with Lunar Software v1.0 is as safe, as effective, and substantially equivalent to the predicate device.