November 14, 2025

EOS imaging
% Mathilde Masurel
Design Quality and Regulatory Affairs Specialist
32 rue blanche
PARIS, 75009
FRANCE

Re: K251078
Trade/Device Name: AutoDensity
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: April 8, 2025
Received: October 14, 2025

Dear Mathilde Masurel:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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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)*
K251078

Device Name
AutoDensity

Indications for Use *(Describe)*
AutoDensity is a post-processing software intended to estimate spine Bone Mineral Density (BMD) from EOSedge dual energy images for orthopedic pre-surgical assessment applications. It is an opportunistic tool that enables immediate assessment of bone density from EOSedge images acquired for other purposes.
AutoDensity is not intended to replace DXA screening. Suspected low BMD should be confirmed by a DXA exam.
Clinical judgment and experience are required to properly use the software.

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

K251078

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

1 SUBMITTER

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Date Summary Prepared: November 10, 2025

2 DEVICE

Trade Name:	AutoDensity
Common or Usual Name:	Medical Image processing software for Bone Mineral Density evaluation
Classification Name:	Medical Image Management and Processing System (21 C.F.R. § 892.2050)
Regulatory Class:	Class II
Product Code:	QIH

3 LEGALLY MARKETED PREDICATE DEVICE

510(k)	Product Name	Clearance Date
K251747	VEA Align	August 2025

4 REFERENCE DEVICE

510(k)	Product Name	Clearance Date
K072847	APEX Software for QDR X-Ray Bone Densitometers	December 2007

5 DEVICE DESCRIPTION

Based on EOSedge™ system's images acquired with the dual energy protocols cleared in K233920, AutoDensity software provides an estimate of the Bone Mineral Density (BMD) for L1-L4 in EOSedge AP radiographs of the spine. These values are used to aid in BMD estimation in orthopedic surgical planning workflows to help inform patient assessment and surgical decisions. AutoDensity is opportunistic in nature and provides BMD information with equivalent radiation

dose compared to the EOSedge images concurrently acquired and used for general radiographic exams. AutoDensity is not intended to replace DXA screening.

6 INDICATIONS FOR USE

AutoDensity is a post-processing software intended to estimate spine Bone Mineral Density (BMD) from EOSedge dual energy images for orthopedic pre-surgical assessment applications. It is an opportunistic tool that enables immediate assessment of bone density from EOSedge images acquired for other purposes.

AutoDensity is not intended to replace DXA screening. Suspected low BMD should be confirmed by a DXA exam.

Clinical judgment and experience are required to properly use the software.

7 TECHNOLOGICAL COMPARISON TO PREDICATE

The subject device was compared to its predicate device and reference device in intended use, indications for use, design, function and technology and it was demonstrated that it is substantially equivalent. Any technological differences within this 510(k), between the subject device and the predicate or reference device, do not impact substantial equivalence, or safety and effectiveness.

Specification	Predicate	Reference Device	Subject Device	Substantial Equivalence Discussion
Manufacturer	EOS imaging	Hologic	EOS imaging	
System	VEA Align (K251747)	APEX Software for QDR X-Ray Bone Densitometers (K072847)	AutoDensity	
Product Code	QIH	KGI	QIH	Yes, same as predicate
Device Classification	II	II	II	Yes, same as predicate
Device Classification Name	Medical Image Management and Processing System	Bone Densitometer	Medical Image Management and Processing System	Yes, same as predicate
Regulation Number	§892.2050	§892.1170	§892.2050	Yes, same as predicate
Intended use / Indications	This cloud-based software is intended for orthopedic applications in both pediatric and adult populations. 2D X-ray images acquired in EOS imaging's imaging systems is the foundation and resource to display the interactive landmarks overlayed on the frontal and lateral images. These landmarks are available for users to assess patient-specific global alignment. For additional assessment, alignment parameters compared to published normative values may be available. This product serves as a tool to aid in the analysis of spinal deformities and degenerative diseases, and lower limb alignment disorders and deformities through precise angle and length measurements. It is	The APEX for QDR X-Ray Bone Densitometers is indicated for the estimation of bone mineral density (BMD), comparison of measured variables obtained from a given QDR scan to a database of reference values, the estimation of fracture risk, vertebral deformity assessment, body composition analysis, and discrimination of bone from prosthetics using the Hologic QDR® X-Ray Bone Densitometers. IVA scans are intended for the visualization or quantitative assessment of vertebral body deformities. IVA also allows the visualization of abdominal aortic calcifications and, if present, clinical correlation may be advised since abdominal aortic calcification may be associated with cardiovascular disease.	AutoDensity is a post-processing software intended to estimate spine Bone Mineral Density (BMD) from EOSedge dual energy images for orthopedic pre-surgical assessment applications. It is an opportunistic tool that enables immediate assessment of bone density from EOSedge images acquired for other purposes. AutoDensity is not intended to replace DXA screening. Suspected low BMD should be confirmed by a DXA exam. Clinical judgment and experience are required to properly use the software.	Yes, the subject device intended use/indications for use are substantially equivalent to the predicate device as both devices intended/indicated to provide clinical parameters from X-ray images acquired by EOS imaging system (EOSedge) for orthopedic pre-surgical assessment applications (alignment parameters for the predicate and BMD for the subject device).

Specification	Predicate	Reference Device	Subject Device	Substantial Equivalence Discussion
Manufacturer	EOS imaging	Hologic	EOS imaging	
System	VEA Align (K251747)	APEX Software for QDR X-Ray Bone Densitometers (K072847)	AutoDensity	
	suitable for use with adult and pediatric patients aged 7 years and older. Clinical judgment and experience are required to properly use the software			
Contraindications	VEA Align is contraindicated for cases with vertebrae with severe congenital deformities (e.g., hemivertebrae, spina bifida, etc.).	Pregnancy and the use of contrast agents within the past 7 days are contraindicated.	AutoDensity is contraindicated for cases with supernumerary/ missing vertebrae.	Yes, the updated contraindications do not change the Intended Use. Both devices treat the same patient population and compute clinical parameters from X-ray images acquired by EOSedge system for orthopedic applications. While contraindications are different, this is not critical to the proposed device's functionality.
Technical Characteristics	AutoDensity software runs in a cloud-environment.	APEX software runs on QDR X-Ray Bone Densitometers.	AutoDensity software runs in a cloud-environment.	Yes, same as the predicate.
	VEA Align generates spine landmarks from 2D X-ray images acquired with EOSedge system, used to compute alignment clinical parameters.	The Hologic APEX software generates a range of reports and images utilizing the DXA data acquired with the Hologic QDR systems. It can display the DXA measurements along with a representative color image mapping of bone and soft tissue.	AutoDensity generates bone mineral density information utilizing the dual-energy images acquired with the EOSedge system. It computes bone mineral density measurements from "aluminum" and "PMMA" images: • Aluminum image is bone-equivalent density,	Yes, the subject device is substantially equivalent to the predicate device as they both used EOSedge images to compute clinical parameters. The subject device is also equivalent to the reference device as they both enable bone mineral assessments to be identified from bone-equivalent and tissues-equivalent images.

Specification	Predicate	Reference Device	Subject Device	Substantial Equivalence Discussion
Manufacturer	EOS imaging	Hologic	EOS imaging	
System	VEA Align (K251747)	APEX Software for QDR X-Ray Bone Densitometers (K072847)	AutoDensity	
			• PMMA image is soft tissue-equivalent density.	
	The software allows: Assessment of patient spinal global alignment.	The software allows: • Assessment of bone density with lumbar spine, double hip and wrist examinations. • Diagnosis of vertebral fractures using low-dose spinal imaging. • Instant quantification of bone quality of a lumbar spine examination. Other functionalities are available on the system that are not described in this comparison table.	The software allows: Assessment of bone density with lumbar spine.	Yes, the subject device is substantially equivalent to the reference device as they both assess bone mineral density of lumbar spine.
Principles of Operation	VEA Align workflow is divided into the following steps: • Data Acquisition • Data Computation • Report Generation	APEX software workflow is divided into the following main steps: • Data Acquisition, • Data Computation, • Report Generation.	AutoDensity workflow is divided into the following main steps: • Data Ingestion, • Data Computation, • Report Generation.	Yes, same
Device Input	X-ray images from EOS and EOSedge systems	Dual-energy X-ray images	Dual-energy X-ray images from EOSedge systems	Yes, the subject device is substantially equivalent to the predicate device as they both uses EOSedge images as input.
Device Output	VEA Align processes data and generates:	APEX software processes data and generates:	AutoDensity processes data and generates:	Yes, the subject device is substantially equivalent to the predicate device as they both

Specification	Predicate	Reference Device	Subject Device	Substantial Equivalence Discussion
Manufacturer	EOS imaging	Hologic	EOS imaging	
System	VEA Align (K251747)	APEX Software for QDR X-Ray Bone Densitometers (K072847)	AutoDensity	
	• Preview of the spine used to compute landmarks and clinical parameters • Alignment clinical parameters	• Previews with vertebrae used for BMD computation, • BMD measurement.	• Previews with vertebrae used for BMD computation, • BMD measurements.	generate clinical parameters and preview of the images used to compute them. The subject device is also equivalent to the reference device as they both process data and generate previews and BMD measurements.
Regions of Interest detection	VEA Align computes landmarks associated with vertebral centers and endplates needed to calculate coronal and sagittal clinical parameters.	Region of interest detection is done for at least the following anatomical body part: • Spine (lumbar vertebrae): ○ Frontal: L1, L2, L3 and L4	Region of interest detection is done for the following anatomical body part: • Spine (lumbar vertebrae) ○ Frontal: L1, L2, L3 and L4.	Yes, the subject device is substantially equivalent to the reference device as they both perform region of interest detection on similar anatomical body parts.
Provides Bone Mineral Density Value	N/A	Bone Mineral Density values are computed for at least the following anatomical body part: • Spine (lumbar vertebrae): ○ Frontal: L1, L2, L3, L4 and total BMD	Bone Mineral Density values are computed for the following anatomical body part: • Spine (lumbar vertebrae): ○ Frontal: L1, L2, L3, L4 and total BMD	Yes, the subject device is substantially equivalent to the reference device in that Bone Mineral Density values are also computed using L1 to L4.
Information Provided in the Report	Patient information Examination information Landmark detection Alignment clinical parameters	Patient information Examination information ROI detection Bone Mineral Density Values	Patient information Examination information ROI detection Bone Mineral Density Values	Yes, same

8 PERFORMANCE DATA

Non-clinical and clinical performance testing has been completed on the subject AutoDensity device to demonstrate substantial equivalence to the predicate device and reference device. The safety and effectiveness of AutoDensity's BMD output have not been established for the pediatric population.

The following V&V testing was performed on the subject device:

A. Verification activities covering the following
   - Design input review
   - Unit testing
   - Software integration
   - System integration

B. Region of Interest (ROI) Performance Evaluation
   To assess the standalone performance of the AI algorithm of AutoDensity, the test was performed with:
   - A dedicated test data set containing different data from the training data set. Specifically, the test data set is not a sampling of the training data set, has never been used for the algorithm training or for tunning the algorithm and leakage between training and test data sets did not occur.
   - A ground truth established for all cases following a 3 truther majority voting principle with input from a senior US board certified expert radiologist (gold standard).
   - A global acceptance criterion to assess the performance of the AI algorithm predictions regarding the ground truth.
   - Subgroup analyses to assess bias and generalizability.

   Training data information
   The AI algorithm was trained using 4,679 3D reconstructions and 9,358 corresponding EOS (K152788) or EOSedge (K233920) biplanar 2D X-ray images was selected to only keep relevant images with the fields of view of interest, at a variety of sites from 2007-2024. This population characteristics cover the intended use population.

   Testing data information
   The testing data set consisted of 129 patients and the demographic characteristics cover the intended use population. All cases were obtained from EOSedge systems (K233920) using low dose, single energy acquisition protocols.

   Subgroup definition (generalizability)
   Subgroup testing was performed to demonstrate generalizability of the algorithm:

Type	Subgroup	Category
Demographics*	Age	Pediatric
		Adult
	Sex	Male
		Female
Image Acquisition*	Field of View	Full Spine
		Full Body
Data Collection Site	Country	US
		OUS
Disease Conditions	Degenerative – Spine	Normal-Mild
		Moderate
		Severe
Lumbar Morphometry (Levels evaluated separately; maximum angle compared to view-plane)	Vertebral Sagittal Angle for L1, L2, L3 and L4 each, and maximum	Low
		Medium
		High
	Vertebral Axial Rotation (VAR) for L1, L2, L3 and L4 each, and maximum	Low
		Medium
		High

Ground truthing method:
Ground truth ROIs and level identification were established by two trained technologists under the supervision of a senior US board-certified radiologist. The radiologist reviewed the results, selected the more accurate set, and made any necessary adjustments, ensuring that the final ground truth reflected a majority vote with expert adjudication as the gold standard.

Testing method
Testing of the AutoDensity algorithm was performed against the ground truth to evaluate:

- Vertebral Level Identification, assessed based on the % of vertebral levels correctly identified compared to ground truth
- Spine ROI Accuracy, assessed by Dice Coefficient overlap between algorithm predicted ROIs and radiologist ground truth

Testing was performed with images acquired from single energy acquisitions. A bridging study using 30 cases from dual energy acquisitions demonstrated equivalent performance of the ROI algorithm and justified utilization of single energy acquisition images for this purpose.

Acceptance Criteria
The acceptance criteria are used to characterize the performance of the AI algorithm feature. As such, the following acceptance criteria were defined:

- Vertebral Level Identification Accuracy
    - Percent of levels correctly identified ≥ 90%

- Spine ROI Accuracy:
  - Lower boundary of 95% CI of mean Dice Coefficient ≥ 0.80

Testing summary
Testing confirms that the AutoDensity ROI detection algorithm meets performance thresholds. The high accuracy in both vertebral level identification and ROI detection combined with strong subgroup performance, supports its clinical utility and generalizability for the AutoDensity intended use population.

C. Bench performance testing
Precision and agreement of BMD measurements in phantoms, compared to the reference device.

- BMD precision was assessed by measuring three phantoms ten times without repositioning. Results met the acceptance criterion (CV% < 1.5%), indicating equivalent precision performance to the same phantoms scanned with the reference device.
- BMD agreement was assessed by measuring one phantom analyzed with AutoDensity and the reference device. Bland-Altman analysis showed a maximum BMD difference of 0.057 g/cm^2 for the high BMD phantom vertebra, and a difference of less than 0.018 g.cm^2 for the vertebrae within a clinically relevant range of BMD for the specified orthopedic planning workflow for pre-surgical patient evaluation of suspected low BMD.

D. Clinical performance testing
Clinical studies were performed to demonstrate the performance of AutoDensity with respect to:

- Precision of AutoDensity BMD measurements in 30 human subjects undergoing repeated measurements with repositioning. AutoDensity precision CV% was 2.23% [95% CI: 1.78%, 2.98%] with the patient in a weight-bearing standing position, in contrast to modalities where the patient is lying supine and stabilized with positioning aids which yields higher precision for DXA densitometers. Despite the difference in mode of operation, AutoDensity precision performance is within the range of acceptable clinical limits for the specified pre-surgical orthopedic patient assessment.
- Bland-Altman agreement between AutoDensity and the reference device BMD measurements in a clinical population of 253 subjects representative of the intended use population, including 65% US subjects and 35% French subjects; 68% were female; the proportion of subjects aged below 50 years was 62% and above 50 was 38%; 56% of subjects had BMI below 25, 34% between 25-30 and 10% between 30-35. Bland-Altman bias was 0.045 g/cm^2 and limits of agreement (LoA) were [-0.088 g/cm^2, 0.178 g/cm^2]. Bland-Altman bias and LoA for AutoDensity compared to the reference device were equivalent to published Bland-

Altman agreement between other commercial bone densitometers in similar clinical study populations.

The results demonstrate that the subject AutoDensity device is substantially equivalent to the predicate and reference device for nonclinical and clinical testing.

9 CONCLUSION

Based on the information provided in this 510(k) submission, it was determined that the subject device, AutoDensity, is substantially equivalent to the legally marketed predicate device and reference device with regards to indications for use, intended use, design, technology, and performance.