October 27, 2026

Naitive Technologies, Ltd.
% Ioan Wigley
RAQA Lead
C/O Mishcon De Reya
Four Station Sq.
CAMBRIDGE, CB1 2GE
UK

Re: K261512
Trade/Device Name: OsteoSight Spine (v1)
Regulation Number: 21 CFR 892.1171
Regulation Name: Radiology Software For Opportunistic Evaluation Of Low Bone Mineral Density
Regulatory Class: Class II
Product Code: SAO
Dated: September 28, 2026
Received: September 28, 2026

Dear Ioan Wigley:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261512

Please provide the device trade name(s).

OsteoSight Spine (v1)

Please provide your Indications for Use below.

OsteoSight™ is a software application intended for use opportunistically with standard frontal radiographs of the lumbar spine (AP), thoracic spine (AP), and chest (PA) performed in patients aged 50 years and older. OsteoSight provides a notification in the form of a report to aid radiologists and/or physician interpreters in identifying patients with possible low bone mineral density (BMD) at L1-L4 to prompt a clinical assessment of bone health. OsteoSight should not be used to rule out low BMD. Radiologists and referring clinicians should follow recommended practices for screening and assessment, regardless of the absence of an OsteoSight report.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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K261512

510(k) Summary

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

Submitter

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Tel: +44 020 3321 7000

Contact: Ioan Wigley
Date Prepared: September 25th, 2026

Subject Device

Device Name: OsteoSight Spine (v1)
Proprietary Name: OsteoSight™
Classification: Class II
Product Code: SAO
Regulation: 21 CFR 892.1171

Predicate Device

Manufacturer: 16 Bit Inc
Device: Rho
Predicate Number: DEN230023

Indications for Use

OsteoSight™ is a software application intended for use opportunistically with standard frontal radiographs of the lumbar spine (AP), thoracic spine (AP), and chest (PA) performed in patients aged 50 years and older. OsteoSight provides a notification in the form of a report to aid radiologists and/or physician interpreters in identifying patients with possible low bone mineral density (BMD) at L1-L4 to prompt a clinical assessment of bone health. OsteoSight should not be used to rule out low BMD. Radiologists and referring clinicians should follow recommended practices for screening and assessment, regardless of the absence of an OsteoSight report.

Intended Patient Population

OsteoSight is intended to be used on patients aged 50 years and older who receive a standard frontal radiograph of the lumbar spine, thoracic spine, and chest.

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Limitations

- OsteoSight is not intended to replace DXA and does not diagnose osteopenia or osteoporosis. Radiologists and referring clinicians should follow recommended practices for screening and assessment
- OsteoSight cannot be used to rule out low BMD. In certain situations, OsteoSight may not return a report. This does not mean that the patient being assessed is not at risk of low bone mineral density. Radiologists and referring clinicians should follow recommended practices for screening and assessment.
- The absence of an OsteoSight report should not be considered as a negative finding.

1 Device Description

General Description

OsteoSight Spine is an AI-enabled software as a medical device (SaMD) that processes standard anteroposterior (AP) or posteroanterior (PA) radiographs of the lumbar spine, thoracic spine, and chest in patients aged 50 years and older.

OsteoSight Spine operates via integration with a host integration platform that facilitates the secure transfer of DICOM images and associated metadata between OsteoSight Spine and clinical imaging systems. As soon as OsteoSight Spine receives a DICOM path from the host integration platform, it automatically retrieves the file from the DICOM path and begins image analysis.

OsteoSight Spine checks that the input radiograph is a standard AP or PA radiograph of the lumbar spine, thoracic spine, or chest, and then estimates T-score for the L1-L4 vertebrae. If an analyzed image has an estimated T-score that is equal to or greater than a pre-specified threshold, an OsteoSight Spine report will not be generated or sent to the interpreting physician. If an analyzed image has an estimated T-score that is less than a pre-specified threshold, the interpreting physician will receive an OsteoSight Spine report, via the host integration platform, indicating that the patient is at risk of having low BMD. Based on the OsteoSight report and other clinical information the physician may have on the patient, physicians may be prompted to conduct further tests such as a bone health assessment.

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Table 1. Comparison of Technological Characteristics & Intended Use to Predicate Device

	Subject Device	Predicate Device	Comparison of Differences
Image Modality	Radiographs (X-Ray)	Radiographs (X-Ray)	Same
Anatomical area of Interest	Lumbar spine, Thoracic spine, Chest	Lumbar spine, Thoracic spine, Chest, Pelvis, Knee, Hand/wrist	The subject device's scope of anatomy is a subset of the predicate's. Narrowing the input scope does not alter the fundamental intended use (opportunistic BMD screening from standard radiographs).

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Indications for Use	OsteoSight™ is a software application intended for use opportunistically with standard frontal radiographs of the lumbar spine (AP), thoracic spine (AP), and chest (PA) performed in patients aged 50 years and older. OsteoSight provides a notification in the form of a report to aid radiologists and/or physician interpreters in identifying patients with possible low bone mineral density (BMD) at L1-L4 to prompt a clinical assessment of bone health. OsteoSight should not be used to rule out low BMD. Radiologists and referring clinicians should follow recommended practices for screening and assessment, regardless of the absence of an OsteoSight report.	Rho is a software application intended for use opportunistically with standard frontal radiographs of the lumbar spine, thoracic spine, chest, pelvis, knee, or hand/wrist performed in patients aged 50 years and older. Rho provides a notification in the form of a report to aid radiologists and/or physician interpreters in identifying patients with possible low bone mineral density (BMD) at L1-L4 or the femoral neck to prompt a clinical assessment of bone health. Rho should not be used to rule out low BMD. Radiologists and referring clinicians should follow recommended practices for screening and assessment, regardless of the absence of Rho report.	Equivalent intended use. The subject device's anatomical scope is a subset of the predicate's. Narrowing the range of accepted input image types does not alter the fundamental intended use (opportunistic BMD screening from standard radiographs) and does not raise different questions of safety or effectiveness, as the clinical output, intended user, patient population, and use environment remain identical.

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Intended User	Physicians	Physicians	Same - The intended users are Radiologists and/or physician interpreters.
Target Patient Population	Adults ≥ 50 years who undergo an X-ray as part of their standard of care	Adults ≥ 50 years who undergo an X-ray as part of their standard of care	Same
Device Use Environment	Intended for use in professional clinical settings (hospital radiology departments, outpatient imaging centres) by qualified physicians; reports delivered to PACS for review alongside other clinical information. Not for home use.	Intended for use in a professional clinical setting by qualified physicians. Rho is intended for the opportunistic screening of frontal spine x-rays, the analyzed x-rays were originally acquired for un-related clinical indications. A Rho report can then be reviewed alongside any other pertinent clinical information on the patient to make an informed diagnostic decision.	Same use environment in clinical setting, user, and workflow integration. Device deployment-model differences are addressed in the Deployment Environment row below and does not raise different questions of safety and effectiveness as both are delivered with equivalent cybersecurity controls (see Cybersecurity section below).
Design: Purpose	To opportunistically analyze standard frontal radiographs of the spine and chest performed in patients aged 50 years and older. The algorithm presents a binary output to indicate whether or not	To opportunistically analyze standard anteroposterior (AP) radiographs of the spine, chest, pelvis, knee, hand or wrist performed in patients aged 50 years and older. The algorithm	Same design purpose — both devices serve opportunistic BMD-risk identification with output framed as a clinical-assessment prompt.

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	the patient likely has low bone mineral density (BMD) at L1-L4. The device output is a binary at-risk notification delivered as a PACS-integrated report to aid interpreting physicians in identifying patients with possible low BMD to prompt a clinical assessment of bone health; the device does not provide a diagnosis, does not recommend treatment, and is not intended to replace a screening programme.	presents a binary output to indicate whether or not the patient likely has low BMD at either the femoral neck or L1-L4. A Rho Report is generated for positive cases that can be sent back to the PACS for physician interpretation or viewed through a browser-based interface. Rho provides a notification in the form of a report to aid radiologists and/or physician interpreters in identifying patients with possible low bone mineral density (BMD) at the femoral neck to prompt a clinical assessment of bone health.	

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Design: Image Analysis and Quantification	OsteoSight takes as input a digital X-ray from the listed anatomical regions and applies a two-stage processing pipeline; (1) Image qualification — to determine whether the input radiograph is suitable for BMD inference and screens images for incorrect anatomical view. This uses a classifier (DINO Vision Transformer backbone + MLP classifier head). Radiographs that fail qualification are excluded from inference; no output is returned to the user. (2) BMD inference — secondly, the device generates an predicted T-score from the radiograph using a DINO ViT backbone + MLP classifier head. This value is compared against a pre-defined operating point corresponding to low BMD; if the predicted value is below the operating point, the	Rho takes as input a digital X-ray and outputs an inferred Bone Mineral Density (BMD) from the listed anatomical regions. Rho uses a series of algorithms and processing steps from which a 'Rho score' is generated, which corresponds with the likelihood of low BMD. The clinically justified ground truth for establishing whether a patient has low BMD is defined as a T-score measurement of <-1.0 standard deviations (SD) in the femoral neck or L1-L4 vertebrae from a DXA scan. The BMD is measured at the femoral neck of individuals using DXA and then converted to a T-score according to NHANES. The performance of the Rho score to predict low BMD, is compared to this ground truth value.	The predicate's internal computational methods are proprietary and not publicly available, this substantial equivalence argument does not rely on method-level equivalence. Equivalence is claimed on (a) identical intended use, (b) identical clinically justified ground truth (DXA T-score < -1.0 SD), and (c) comparable performance against that ground truth.

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	device returns a binary 'at risk of low BMD' notification. The predicted value is internal to the device and not returned to the user. The operating point is a fixed scalar selected a priori on the model tuning dataset to maximize the sum of sensitivity and specificity.		
Machine Learning Methodology	Supervised Machine Learning (ML), algorithms locked at submission	Supervised Machine Learning (ML), algorithms locked at submission.	Same, both device's algorithms are locked at the point of submission.
Image Source	DICOM Source (e.g., imaging device, intermediate DICOM node, PACS system, etc.)	DICOM Source (e.g., imaging device, intermediate DICOM node, PACS system, etc.)	Same
Clinical Output	Analysis Results Report	Analysis Results Report	Same
Clinical Findings	Binary clinical finding; 'patient is at risk of low BMD' (positive notification) or no notification returned (negative).	Same.	Same.

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	The output report is a screening prompt, not a diagnosis; not intended to replace DEXA-based screening or rule-out low BMD.		
Deployment Environment	OsteoSight can be installed in the cloud, via a host integration platform, which may be within the existing secured network of a clinical site. OsteoSight consists of a number of microservices deployed through container orchestration services such as Docker.	Rho can be installed on-premise or in the cloud, however, it must be within your existing secured network. All traffic to and from Rho can be monitored and controlled by you. Rho consists of a DICOM node, database and a number of microservices deployed through container orchestration services like Docker Compose and Kubernetes.	Subject device is cloud-only; predicate offers both cloud and on-premise. This deployment-model difference does not change the intended use, clinical output, or safety profile.
Human Factors	*OsteoSight Spine* has been developed under design controls in compliance with IEC 62366-1, 'Application of usability engineering to medical devices', and FDA guidance 'Applying Human Factors and Usability Engineering to Medical Devices Guidance for	Rho was developed under design controls and approved based on its compliance to the FD&C Act including validation of its interfaces and risk controls.	Both devices produce a report for physician interpretation within their existing clinical workflow.

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	Industry and Food and Drug Administration Staff'.		
Standards Met	*OsteoSight Spine* has been developed in accordance with applicable design standards; ISO 14971, BS EN 62366 and IEC 62304.	No publicly available information.	*OsteoSight Spine* was developed in accordance with applicable design standards; ISO 14971, BS EN 62366 and IEC 62304.
Materials	*Not applicable — OsteoSight Spine is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.*	Not applicable — Rho is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	*Same.*
Biocompatibility	Not applicable — *OsteoSight Spine* is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Not applicable — Rho is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Same
Compatibility with the environment and other devices	*OsteoSight Spine* processes DICOM images in a software-only configuration and does not require physical integration with imaging equipment.	Rho processes DICOM images in a software-only configuration and does not require physical integration with imaging equipment.	Both devices function as DICOM-input software services within the institution's existing imaging infrastructure. No physical integration with imaging hardware required for either device.

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	OsteoSight Spine has been validated for its intended use environment.		
Cybersecurity	*OsteoSight Spine* has been developed under design control requirements and within the company's quality system including compliance with applicable cybersecurity standards and guidance. *OsteoSight Spine* is PACS-integrated, cloud-or-on-premise deployable, network-connected, and processes DICOM and patient data. See 'Predicate Devices cleared using well-established methods' section for guidance and standards applied during the development of *OsteoSight Spine*.	The predicate is PACS-integrated, cloud-or-on-premise deployable, network-connected, and processes DICOM and patient data.	Both *OsteoSight Spine* and predicate device; are network-connected, process DICOM images and integrate with PACS systems. Any cybersecurity control that is necessary for the predicate is also necessary for the subject device.
Sterility	Not applicable — OsteoSight Spine is a software-only device with no hardware, material, electrical, mechanical, chemical,	Not applicable — Rho is a software-only device with no hardware, material, electrical,	Same

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	thermal, radiation, or sterility characteristics.	mechanical, chemical, thermal, radiation, or sterility characteristics.	
Electrical Safety	Not applicable — *OsteoSight Spine* is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Not applicable — Rho is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Same
Mechanical Safety	Not applicable — *OsteoSight Spine* is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Not applicable — Rho is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Same
Chemical Safety	Not applicable — *OsteoSight Spine* is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Not applicable — Rho is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Same
Thermal Safety	Not applicable — *OsteoSight Spine* is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Not applicable — Rho is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Same
Radiation Safety	Not applicable — *OsteoSight Spine* is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Not applicable — Rho is a software-only device with no hardware, material, electrical, mechanical, chemical, thermal, radiation, or sterility characteristics.	Same

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2 Performance Data

2.1 Sterilization and Shelf Life

N/A – Not applicable to the subject device.

2.2 Biocompatibility Testing

N/A – Not applicable to the subject device.

2.3 Electrical Safety and Electromagnetic Compatibility (EMC)

N/A – Not applicable to the subject device.

2.4 Software Verification and Validation

OsteoSight software documentation and software verification and validation testing demonstrate that the device meets all requirements for basic documentation level as outlined in the FDA guidance documents “Content of Premarket Submissions for Device Software Functions” and “Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions”.

2.5 Mechanical Testing

N/A – Not applicable to the subject device.

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2.6 Animal Studies

N/A – No animal studies were conducted as part of this application.

2.7 Clinical Studies

Prospective clinical studies were not conducted as part of this application to demonstrate safety and effectiveness of the device. Clinical performance assessment for the device is based on a retrospective analysis of multi-center studies to compare sensitivity and specificity of the device with the accepted gold standard, Dual-Energy X-ray Absorptiometry (DXA), with pre-specified performance goals.

Ground truth low BMD is defined as a T-score of < -1.0 SD as measured at L1-L4 from a DXA scan acquired within 12 months. The datasets used for validation included previously acquired X-rays that included paired DXA T-scores.

Table 2. Co-primary and secondary endpoints results. Diagnostic accuracy of OsteoSight showing sensitivity, specificity, and AUROC with 95% confidence intervals.

Population	N	AUROC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
OsteoSight Intended Use Population	3599	0.84 (0.83–0.85)	0.51 (0.49–0.54)	0.91 (0.90–0.92)

Table 3. Diagnostic accuracy of OsteoSight showing sensitivity, specificity, and AUROC with 95% confidence intervals across patient demographic subgroups.

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Group	N	AUROC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Sex				
Females	3190	0.84 (0.82–0.85)	0.52 (0.49–0.54)	0.91 (0.89–0.92)
Males	409	0.85 (0.81–0.89)	0.45 (0.36–0.54)	0.92 (0.89–0.95)
Age group (years)				
50-59	666	0.84 (0.81–0.87)	0.43 (0.37–0.49)	0.93 (0.90–0.95)
60-69	1417	0.85 (0.83–0.87)	0.53 (0.49–0.57)	0.92 (0.90–0.93)
70-79	1084	0.83 (0.80–0.85)	0.51 (0.47–0.56)	0.89 (0.87–0.91)
80+	432	0.84 (0.81–0.88)	0.59 (0.51–0.66)	0.89 (0.85–0.92)
BMI (kg/m2)				
< 18	52	n/a	0.73 (0.59–0.84)	1.00 (0.65–1.00)
18-25	859	0.82 (0.79–0.85)	0.59 (0.55–0.63)	0.85 (0.81–0.89)
25-30	1151	0.81 (0.78–0.84)	0.52 (0.48–0.57)	0.89 (0.86–0.91)
≥ 30	1479	0.83 (0.81–0.85)	0.37 (0.32–0.41)	0.94 (0.92–0.95)
Race				
Asian	180	0.83 (0.76–0.89)	0.64 (0.55–0.72)	0.85 (0.75–0.92)
Black or African American	418	0.79 (0.74–0.84)	0.47 (0.39–0.56)	0.89 (0.85–0.92)
Hispanic	739	0.85 (0.82–0.88)	0.49 (0.44–0.54)	0.93 (0.90–0.95)
White	2262	0.84 (0.83–0.86)	0.51 (0.48–0.54)	0.91 (0.89–0.92)
Region				
Midwest	338	0.80 (0.75–0.85)	0.64 (0.55–0.72)	0.79 (0.73–0.84)
Northeast	118	0.86 (0.79–0.92)	0.60 (0.47–0.72)	0.94 (0.85–0.98)
South	3105	0.85 (0.83–0.86)	0.49 (0.47–0.52)	0.92 (0.91–0.93)

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West	38	0.93 (0.83–1.00)	0.81 (0.57–0.93)	0.91 (0.72–0.97)

Table 4. Diagnostic accuracy of OsteoSight showing sensitivity, specificity, and AUROC with 95% confidence intervals across X-ray hardware manufacturer and settings subgroups.

Group	N	AUROC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
X-ray Hardware Manufacturer				
Agfa	1	n/a	n/a	n/a
Canon inc.	75	0.79 (0.68–0.90)	0.62 (0.45–0.77)	0.86 (0.73–0.93)
Carestream	16	n/a	0.67 (0.21–0.94)	0.69 (0.42–0.87)
Fujifilm	122	0.76 (0.66–0.86)	0.67 (0.50–0.80)	0.73 (0.63–0.81)
GE Healthcare	119	0.82 (0.74–0.90)	0.74 (0.60–0.84)	0.84 (0.73–0.90)
Kodak	1	n/a	n/a	n/a
Konica Minolta	2864	0.85 (0.84–0.87)	0.49 (0.47–0.52)	0.93 (0.91–0.94)
Oehm Und Rehbein Gmbh	1	n/a	n/a	n/a
Philips	41	0.92 (0.83–0.99)	0.67 (0.44–0.84)	0.96 (0.79–0.99)
Samsung	180	0.80 (0.74–0.87)	0.62 (0.52–0.72)	0.88 (0.80–0.93)
Siemens	165	0.83 (0.76–0.89)	0.39 (0.28–0.51)	0.89 (0.81–0.93)
Swissray	5	n/a	0.50 (0.09–0.91)	1.00 (0.44–1.00)
Thales	2	n/a	1.00 (0.21–1.00)	1.00 (0.21–1.00)
Unknown	3	n/a	0.00 (0.00–0.66)	1.00 (0.21–1.00)
Varian	4	n/a	0.50 (0.09–0.91)	1.00 (0.34–1.00)
X-ray Imaging Settings				

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Imager Pixel Spacing				
Imager Pixel Spacing =< 0.174	648	0.79 (0.76–0.83)	0.57 (0.51–0.63)	0.84 (0.80–0.88)
Imager Pixel Spacing > 0.174	2946	0.85 (0.84–0.86)	0.50 (0.47–0.53)	0.92 (0.91–0.93)
X-ray Voltage				
X-ray Voltage =< 75 kVp	70	0.80 (0.69–0.90)	0.45 (0.30–0.60)	0.88 (0.72–0.95)
X-ray Voltage > 75 kVp	509	0.82 (0.78–0.85)	0.60 (0.53–0.66)	0.86 (0.82–0.90)
X-ray Exposure				
X-ray Exposure =< 22 mAs	328	0.81 (0.76–0.85)	0.51 (0.43–0.60)	0.89 (0.84–0.93)
X-ray Exposure > 22 mAs	94	0.82 (0.71–0.91)	0.61 (0.42–0.76)	0.89 (0.80–0.95)

2.8 Post-Market Performance Monitoring Plan

Monitoring the real-world performance of OsteoSight in the intended patient population will be performed to (a) Monitor relevant performance characteristics and detecting changes in performance; (b) Identify sources of performance changes between validation and real-world environment over time; and (c) Assess the results from the performance monitoring on safety and effectiveness. Data will be collected from clinical sites and healthcare providers and device logs. Performance metrics will be compared to baseline performance as reported above. Any trends in change in performance over time will be evaluated including root cause analysis. Internal reports and customer notifications will be sent where required.

2.9 Special Controls

OsteoSight complies with all applicable special controls for the product code SAO, 892.1171;‘Radiology software for opportunistic evaluation of low BMD’. Compliance has been demonstrated through clinical performance testing, software verification and

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validation, and the provision of a post-market performance management plan. Device labeling also meets the requirements outlined in the special controls.

3 Conclusion

The testing conducted and summarized above demonstrates that OsteoSight performs as intended and supports the determination of substantial equivalence to the predicate device. The testing conducted demonstrates that OsteoSight is as safe and effective as the predicate device and no new questions of safety or effectiveness are raised by OsteoSight.