September 2, 2025

Naitive Technologies Ltd
% Ioan Wigley
Head of RA/QA
c/o Mishcon de Reya
Four Station Square
CAMBRIDGE, CB1 2GE
ENGLAND, UNITED KINGDOM

Re: K251408
Trade/Device Name: OsteoSight™ Hip (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: July 29, 2025
Received: July 30, 2025

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.

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
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)*
K251408

Device Name
OsteoSight™ Hip (v1)

Indications for Use *(Describe)*
OsteoSight™ is a software application intended for use opportunistically with standard anteroposterior (AP) radiographs of the hip or pelvis 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 the femoral neck 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: K251408

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: July 29, 2025

Device

Subject Device: OsteoSight™ Hip (v1)
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 anteroposterior (AP) radiographs of the hip or pelvis 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 the femoral neck 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 AP radiograph of the hip or pelvis.

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

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- 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.
- Absence of an OsteoSight report should not be considered as a negative finding

1 DEVICE DESCRIPTION

General Description
OsteoSight is an AI-enabled software as a Medical Device (SaMD) that processes standard anteroposterior (AP) radiographs of the hip or pelvis in patients aged 50 years and older. The device operates via integration with a host integration platform that facilitates the secure transfer of DICOM images and associated metadata from clinical imaging systems.

OsteoSight applies an AI-enabled algorithm pipeline to estimate bone mineral density (BMD) at the femoral neck. If an estimated BMD is below the pre-specified threshold, OsteoSight generates a report indicating that the patient is at risk of having low BMD. This report is delivered to the interpreting physician via the host integration platform. OsteoSight does not provide a diagnosis or treatment recommendation. If the estimated BMD is above or equal to the pre-specified threshold, no report is generated.

The OsteoSight report is intended to inform physicians and support further clinical evaluation. Physicians may consider additional assessments, such as a comprehensive fracture risk assessment, in conjunction with other clinical information.

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

	Subject Device	Predicate Device	Summary
510(k) number	**TBC**	**DEN230023**	
Legal Manufacturer	**Naitive Technologies Limited**	**16-Bit Inc**	
Device Name	**OsteoSight™**	**Rho**	
Anatomical area of Interest	Pelvis or hip	Lumbar spine Thoracic spine Chest Pelvis Knee Hand/wrist	Both predicate and subject device are indicated for quantification of X-ray images of the pelvis.
Indications for Use	OsteoSight™ is a software application intended for use opportunistically with standard anteroposterior (AP) radiographs of the hip or pelvis performed in patients aged 50 years and older.. OsteoSight™ provides a notification in	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	Equivalent intended use

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	Subject Device	Predicate Device	Summary
	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. 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.	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.	
Intended User	Physician	Physician	Same
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	When reporting the X-ray, the radiologist or physician interpreter can review the OsteoSight	Rho can be installed on-premise or in the cloud, however, it must be within your	Same

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	Subject Device	Predicate Device	Summary
	Report, and, if in agreement, can simply include this finding in their own words. 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 like Docker.	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.	
Design: Purpose	To opportunistically analyze standard anteroposterior (AP) radiographs of the hip or pelvis performed in patients aged 50 years and older. The algorithm presents a binary output to indicate whether the patient likely has low BMD at the femoral neck. An OsteoSight Report is	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 presents a binary output to indicate whether or not the patient likely has low BMD at either the femoral neck or L1-	Same, but fewer anatomical regions.

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	Subject Device	Predicate Device	Summary
	generated for positive cases that can be sent back to the PACS for physician interpretation. OsteoSight provides a notification in the form of a report to aid radiologists and/or physician interpreters to identify patients with possible low bone mineral density (BMD) at the femoral neck to prompt a clinical assessment of bone health.	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.	
Machine Learning Methodology	Supervised Machine Learning (ML)	Supervised Machine Learning (ML)	Same
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	Results Report	Results Report	Same
Clinical Finding	Patients at risk of low BMD	Patients at risk of low BMD	Same

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	Subject Device	Predicate Device	Summary
Image viewing	Result output through a report with no annotation of the original image	Result output through a report with no annotation of the original image	Same
Deployment environment	Results will be presented to a physician in a medical setting, typically via a Picture Archiving and Communication System (PACS).	Results will be presented to a physician in a medical setting, typically via a Picture Archiving and Communication System (PACS).	Same
Human factors	OsteoSight was developed under design controls in compliance with IEC 62366, 'Application of usability engineering to medical devices', and FDA guidance '*Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff*'.	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.	Same
Standards met	OsteoSight was developed in accordance with applicable design standards; ISO 14971, BS EN 62366 and IEC 62304.	No publicly available information.	/
Materials	N/A – Software device only.	N/A – Software device only.	/

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	Subject Device	Predicate Device	Summary
Biocompatibility	N/A – Software device only.	N/A – Software device only.	/
Compatibility with the environment and other devices	OsteoSight processes DICOM images in a software-only configuration and does not require physical integration with imaging equipment. OsteoSight has been validated for its intended use and operational environment.	Rho processes DICOM images in a software-only configuration and does not require physical integration with imaging equipment.	Same
Sterility	N/A – Software device only.	N/A – Software device only.	/
Electrical safety	N/A – Software device only.	N/A – Software device only.	/
Mechanical safety	N/A – Software device only.	N/A – Software device only.	/
Chemical safety	N/A – Software device only.	N/A – Software device only.	/
Thermal safety	N/A – Software device only.	N/A – Software device only.	/
Radiation safety	N/A – Software device only.	N/A – Software device only.	/

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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 document "*Content of Premarket Submissions for Device Software Functions.*"

2.5 Mechanical Testing

N/A – Not applicable to the subject device.

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 the femoral neck from a DXA scan acquired within 12 months The datasets used for validation included previously acquired X-rays that included paired DXA T-scores.

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2.7.1 Intended Use Population

The Intended Use Population, referring to all study subjects who meet the Indications for Use, was made up of de-identified data from six independent cohorts from the US (including the Midwest, Northeast, South, and West). The patient demographics for the Intended Use Population are described in Table 2 with representation across age decades from 50 and above, sex, BMI, and race.

Sensitivity and specificity (with 95% confidence intervals) are reported for the full intended use population. In this analysis, “no result” cases are treated as negative device outputs. AUC cannot be calculated for the full population, as the device does not produce a continuous test statistic (eBMD) in cases with no result.

Table 2. Demographic information of the Intended Use Population. Interquartile range (IQR), Body mass index (BMI), Dual-energy X-ray absorptiometry (DXA), bone mineral density (BMD).

Data	Total
Sample size	3082
Age (Median [IQR]) (min-max)	70.0 [64.0 - 76.0] (50 – 98)
Sex (Female:Male:not reported)	2787:285:10
BMI (Mean +/- SD) (min-max)	29.3 +/- 6.6 (15.1 – 63.8)
DXA FN BMD (Mean +/- SD) (min-max)	0.716 +/- 0.146 (0.134 – 1.535)
Prevalence of Low BMD (%)	66.7%
Time Between Scans (Median [IQR] days)(min-max)	107.5 [31.0 - 207.0] (0 – 365)
Race	Asian: 81 (2.6%); Black or African American: 171 (5.5%); Hispanic: 574 (18.6%); Other/not known: 855 (27.7%); White: 1401 (45.5%)
Manufacturer	Agfa: 2 (0.1%); Canon Inc.: 17 (0.6%); Carestream: 77 (2.5%); Eos Imaging: 2 (0.1%); FUJIFILM: 41

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	(1.3%); GE Healthcare: 22 (0.7%); Iray: 1 (0.0%); Konica Minolta: 1747 (56.7%); Philips: 18 (0.6%); Samsung: 315 (10.2%); Siemens: 655 (21.3%); Swissray: 122 (4.0%); Thales: 2 (0.1%); Varian: 7 (0.2%); Visaris: 54 (1.8%)

When calculated across the entire intended use population, including cases where no result was produced, sensitivity was 0.370 (95% CI 0.349-0.391) and specificity was 0.951 (95% CI 0.936-0.963), as shown in Table 3 below. These results should be considered within the context that OsteoSight, *by design*, removes cases where an ROI cannot be placed on the total hip DXA region.

Table 3. Performance Characterization of OsteoSight in Intended Use Population.

Population	N	Specificity (95% CI)	Sensitivity (95% CI)	AUC (95% CI)
OsteoSight Intended Use Population	3082	0.951 (0.936-0.963)	0.370 (0.349-0.391)	n/a

2.7.2 Intended Use Sub-set

Diagnostic accuracy metrics including sensitivity, specificity, and AUC (with 95% confidence intervals), are reported for a subset of the intended use population in which OsteoSight generated a result.

Among patients in whom a result was generated, the area under the ROC curve (AUC) was **0.837** (95% CI 0.821-0.852). Sensitivity for detecting low BMD was **0.441** (95% CI 0.386-0.487), while specificity was **0.943** (95% CI 0.922-0.961), as shown in Table 4).

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Table 4. Diagnostic Accuracy of OsteoSight in Subset of Intended Use Population that produced a result.

Population	N	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Subset of OsteoSight Intended Use Population that produced a result	2596	0.837 (0.821-0.853)	0.441 (0.386-0.487)	0.943 (0.922-0.961)

All pre-specified acceptance criteria for the co-primary and secondary endpoints in the clinical studies were met.

2.7.3 Sub-Group Analysis – Clinical confounders

Subgroup analyses were performed in both cohorts, stratified by clinical factors and image characteristics, to evaluate generalizability of performance. Specificity, sensitivity, and accuracy measures were calculated in predefined clinical subgroups, using the population in the intended use population (Table 5a, Table 6a) and in which OsteoSight generated a result (negative or positive) (Table 5b, Table 6b).

Table 5a. Diagnostic Accuracy of OsteoSight in predefined clinical subgroups, in the Intended Use Population.

Group	N	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Sex				
Females	2787	n/a	0.373 (0.352-0.395)	0.950 (0.934-0.963)
Males	285	n/a	0.319 (0.249-0.399)	0.957 (0.910-0.980)
Age group (years)				
50-59	418	n/a	0.258 (0.201-0.324)	0.969 (0.938-0.985)
60-69	1012	n/a	0.347 (0.310-0.385)	0.940 (0.912-0.960)
70-79	1045	n/a	0.401 (0.366-0.437)	0.959 (0.930-0.976)
80+	485	n/a	0.489 (0.441-0.537)	0.912 (0.830-0.957)

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BMI (kg/m^2)				
18-25	352	n/a	0.508 (0.452-0.565)	0.906 (0.797-0.959)
25-30	464	n/a	0.442 (0.388-0.498)	0.941 (0.891-0.969)
>30	531	n/a	0.306 (0.253-0.365)	0.960 (0.930-0.978)
Race				
Asian	81	n/a	0.353 (0.250-0.472)	0.923 (0.667-0.986)
Black or African American	171	n/a	0.229 (0.133-0.365)	0.967 (0.919-0.987)
Hispanic	574	n/a	0.414 (0.364-0.465)	0.963 (0.928-0.981)
White	855	n/a	0.375 (0.335-0.416)	0.940 (0.907-0.962)
Other/not known	1401	n/a	0.359 (0.330-0.389)	0.949 (0.922-0.967)
Region				
Midwest	425	n/a	0.283 (0.237-0.333)	0.978 (0.922-0.994)
Northeast	357	n/a	0.258 (0.210-0.312)	0.936 (0.859-0.972)
South	2146	n/a	0.409 (0.383-0.436)	0.952 (0.935-0.965)
West	154	n/a	0.438 (0.355-0.524)	0.885 (0.710-0.960)

Table 5b. Diagnostic Accuracy of OsteoSight in predefined clinical subgroups, using the population in which OsteoSight generated a result.

Group	N	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Sex				
Females	2347	0.840 (0.823-0.856)	0.446 (0.390-0.501)	0.942 (0.921-0.960)
Males	239	0.810 (0.756-0.865)	0.374 (0.130-0.537)	0.948 (0.888-0.991)
Age group (years)				

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50-59	352	0.838 (0.797-0.879)	0.314 (0.199-0.462)	0.964 (0.918-0.995)
60-69	893	0.809 (0.779-0.838)	0.391 (0.325-0.467)	0.932 (0.896-0.961)
70-79	919	0.839 (0.812-0.867)	0.452 (0.332-0.545)	0.952 (0.926-0.978)
80+	428	0.834 (0.784-0.885)	0.552 (0.357-0.721)	0.899 (0.812-0.957)
BMI (kg/m^2)				
18-25	333	0.846 (0.781-0.910)	0.543 (0.182-0.750)	0.906 (0.792-0.981)
25-30	444	0.833 (0.794-0.873)	0.462 (0.351-0.579)	0.938 (0.897-0.979)
>30	508	0.795 (0.757-0.833)	0.321 (0.239-0.407)	0.958 (0.917-0.985)
Race				
Asian	75	0.778 (0.629-0.927)	0.381 (0.095-0.841)	0.917 (0.750-1.000)
Black or African American	133	0.830 (0.753-0.908)	0.344 (0.156-0.562)	0.960 (0.842-1.000)
Hispanic	511	0.861 (0.829-0.893)	0.466 (0.381-0.556)	0.958 (0.911-0.984)
White	1141	0.826 (0.798-0.853)	0.442 (0.281-0.519)	0.938 (0.906-0.968)
Other/not known	736	0.828 (0.798-0.859)	0.437 (0.357-0.555)	0.931 (0.892-0.965)
Region				
Midwest	308	0.849 (0.795-0.902)	0.396 (0.013-0.600)	0.971 (0.912-1.000)
Northeast	288	0.823 (0.761-0.885)	0.316 (0.250-0.667)	0.917 (0.850-1.000)
South	1846	0.845 (0.828-0.863)	0.476 (0.408-0.527)	0.944 (0.919-0.964)
West	154	0.818 (0.721-0.915)	0.438 (0.281-0.844)	0.885 (0.769-1.000)

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Table 6a. Diagnostic Accuracy of OsteoSight across X-ray Machine Manufacturer, in the Intended Use Population.

Group	N	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
X-ray Hardware Manufacturer				
Canon Inc.	17	n/a	0.429 (0.214-0.674)	1.000 (0.439-1.000)
Carestream	77	n/a	0.211 (0.125-0.333)	1.000 (0.839-1.000)
FUJIFILM	41	n/a	0.444 (0.276-0.627)	1.000 (0.785-1.000)
GE Healthcare	22	n/a	0.150 (0.052-0.360)	1.000 (0.342-1.000)
Konica Minolta	1747	n/a	0.431 (0.402-0.461)	0.944 (0.923-0.959)
Philips	18	n/a	0.143 (0.040-0.399)	0.750 (0.301-0.954)
Samsung	315	n/a	0.267 (0.213-0.329)	0.926 (0.854-0.963)
Siemens	655	n/a	0.291 (0.250-0.334)	0.986 (0.959-0.995)
Swissray	122	n/a	0.398 (0.307-0.497)	0.875 (0.690-0.957)
Varian	7	n/a	0.000 (0.000-0.490)	1.000 (0.439-1.000)
Visaris	54	n/a	0.426 (0.295-0.567)	1.000 (0.646-1.000)
X-ray settings				
Imager Pixel Spacing =< 0.174	1190	n/a	0.300 (0.271-0.331)	0.965 (0.938-0.980)
Imager Pixel Spacing > 0.174	1770	n/a	0.428 (0.399-0.457)	0.944 (0.924-0.960)
X-ray Voltage =< 75 kVp	690	n/a	0.283 (0.245-0.325)	0.981 (0.951-0.992)
X-ray Voltage > 75 kVp	541	n/a	0.309 (0.267-0.355)	0.930 (0.868-0.964)
X-ray Exposure =< 22 mAs	618	n/a	0.281 (0.243-0.322)	0.976 (0.931-0.992)

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X-ray Exposure > 22 mAs	609	n/a	0.310 (0.267-0.356)	0.954 (0.915-0.976)

Table 6b. Diagnostic Accuracy of OsteoSight across X-ray Machine Manufacturer, using the population in which OsteoSight generated a result

Group	N	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
X-ray Hardware Manufacturer				
Canon Inc.	12	0.852 (0.611-1.000)	0.667 (0.556-1.000)	1.000 (0.000-1.000)
Carestream	48	0.899 (0.796-1.000)	0.343 (0.257-0.886)	1.000 (0.846-1.000)
FUJIFILM	41	0.918 (0.835-1.000)	0.444 (0.481-0.889)	1.000 (1.000-1.000)
GE Healthcare	17	0.767 (0.495-1.000)	0.200 (0.467-1.000)	1.000 (1.000-1.000)
Konica Minolta	1522	0.842 (0.822-0.862)	0.496 (0.415-0.547)	0.936 (0.907-0.957)
Philips	14	0.455 (0.000-0.952)	0.182 (0.000-1.000)	0.667 (0.000-1.000)
Samsung	244	0.805 (0.744-0.865)	0.343 (0.279-0.640)	0.903 (0.833-1.000)
Siemens	513	0.861 (0.828-0.893)	0.375 (0.070-0.552)	0.982 (0.953-1.000)
Swissray	117	0.811 (0.702-0.921)	0.415 (0.255-0.840)	0.870 (0.739-1.000)
Varian	7	0.833 (0.456-1.000)	0.000 (0.000-1.000)	1.000 (1.000-1.000)
Visaris	54	0.894 (0.783-1.000)	0.426 (0.489-0.957)	1.000 (1.000-1.000)
X-ray settings				
Imager Pixel Spacing =< 0.174	954	0.844 (0.816-0.872)	0.372 (0.274-0.551)	0.955 (0.926-0.984)
Imager Pixel Spacing > 0.174	1545	0.842 (0.822-0.862)	0.492 (0.413-0.544)	0.937 (0.909-0.958)
X-ray Voltage =< 75 kVp	547	0.849 (0.816-0.883)	0.358 (0.300-0.527)	0.976 (0.939-1.000)

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X-ray Voltage > 75 kVp	445	0.823 (0.772-0.874)	0.374 (0.246-0.691)	0.913 (0.859-0.967)
X-ray Exposure =< 22 mAs	496	0.840 (0.799-0.882)	0.362 (0.057-0.625)	0.963 (0.925-0.991)
X-ray Exposure > 22 mAs	492	0.840 (0.802-0.878)	0.366 (0.294-0.558)	0.946 (0.899-0.986)

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, 820.1171;'Radiology software for opportunistic evaluation of low BMD'. Compliance has been demonstrated through clinical performance testing, software verification and 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.