June 10, 2026

Alpha Intelligence Manifolds, Inc.
% Qingzong TSENG
VP, Data Science
2f, # 170, Zhonghe Rd., Zhonghe Dist.
NEW TAIPEI CITY, 235068
TAIWAN

Re: K253192
Trade/Device Name: DeepXray Spina
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 26, 2025
Received: May 11, 2026

Dear Qingzong TSENG:

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 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, 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)*
K253192

Device Name
DeepXray Spina

Indications for Use *(Describe)*
DeepXray Spina is a software application intended for use opportunistically with standard frontal radiographs of the lumbar spine or KUB (kidney, ureter, and bladder) performed in patients aged 50 years and older. DeepXray Spina 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. DeepXray Spina 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 a DeepXray Spina report.
Input Restriction: DeepXray Spina is intended for use with standard frontal radiographs of the lumbar spine or KUB that are suitable for L1–L4 BMD analysis. The device is not intended for use with images in which one or more L1–L4 vertebrae contains: (a) metallic spinal implants or prostheses (e.g., pedicle screws, rods, cages, or total disc replacements); (b) vertebral cement augmentation (e.g., kyphoplasty or vertebroplasty); (c) severe vertebral deformity, fracture, or other structural abnormality that would preclude a valid DXA-based L1–L4 BMD measurement; or (d) extraspinal medical implants overlying the L1–L4 measurement region (e.g., abdominal aortic stent grafts or vascular grafts).

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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K253192 **510(k) SUMMARY**

DeepXray Spina
Alpha Intelligence Manifolds, Inc.

Applicant:	Alpha Intelligence Manifolds, Inc. 2F, No.170, Zhonghe Road, Zhonghe District, New Taipei City, 235068, Taiwan Telephone: +886-2-2240-6570
Date Prepared:	Jun 9, 2026
Device Name:	DeepXray Spina
Regulation Number:	892.1171
Product Code:	SAO
Classification Name:	Radiology software for opportunistic evaluation of low bone mineral density
Device Class:	Class II
Review Panel:	Radiology
Predicate Devices:	16 Bit Rho (DEN230023)

Device Description

DeepXray Spina is a software-only medical device (SaMD) that identifies patients with Low BMD (T-score ≤ –2.5) from standard frontal radiographs of the lumbar spine or KUB (kidney, ureter, and bladder), acquired as Computed Radiography (CR) or Digital Radiography (DR). The device does not interact with patients directly, does not modify the acquisition system, and does not control any life-sustaining devices.

The scientific principle underlying DeepXray Spina is radiogrammetry: bone mineral density (BMD) is inferred from the structural and textural features of standard radiographs rather than measured by absorptiometric principles. The device employs locked artificial intelligence / machine-learning (AI/ML) algorithms, trained and validated against dual-energy X-ray absorptiometry (DXA) ground truth, to estimate the aggregate L1–L4 BMD, matching the same

anatomical region and aggregation convention used in standard DXA lumbar spine measurements. The estimated BMD is then converted internally to a T-score against the U.S. National Health and Nutrition Examination Survey (NHANES) young-adult non-Hispanic white female reference population, as recommended by the International Society for Clinical Densitometry (ISCD), and thresholded at −2.5 to produce the user-facing binary classification. The intermediate L1–L4 BMD and T-score values are not displayed.

The device output is a binary classification: "Low BMD" (internal L1–L4 T-score ≤ −2.5) or "Not Suspected" (internal L1–L4 T-score > −2.5). A DeepXray Spina report is generated for positive cases. For cases where the algorithm outputs a negative result, no report is generated, and neither the radiologist nor the referring physician receives any device output. Each generated report displays a vertebral region-of-interest (ROI) overlay on the original radiograph, enabling the clinician to visually verify anatomical localization and the absence of severe artifacts before acting on the result. An automated Quality-Control (QC) function detects technical and anatomical exclusion conditions within the L1–L4 region and flags input images with potential quality issues.

DeepXray Spina is installed as an add-on module to the cleared DeepXray system (K223621). The software is deployed within Docker containers on a Linux server inside the institution's local network and shares the same Input & Report Server (IRS) as DeepXray. The IRS manages DICOM inputs, performs basic tag and image-type filtering, and delivers outputs through either a web-based report accessible from a browser or a static DICOM-format report returned to the institution's PACS. The DeepXray Spina pipeline runs inside the Inference Engine (IE) of the existing DeepXray system and includes anatomical ROI localization, landmark identification, BMD estimation, automated QC checks, and report generation.

Indications for Use

DeepXray Spina is a software application intended for use opportunistically with standard frontal radiographs of the lumbar spine or KUB (kidney, ureter, and bladder) performed in patients aged 50 years and older. DeepXray Spina 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. DeepXray Spina 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 a DeepXray Spina report.

Input Restriction: DeepXray Spina is intended for use with standard frontal radiographs of the lumbar spine or KUB that are suitable for L1–L4 BMD analysis. The device is not intended for use with images in which one or more L1–L4 vertebrae contains: (a) metallic spinal implants or prostheses (e.g., pedicle screws, rods, cages, or total disc replacements); (b) vertebral cement augmentation (e.g., kyphoplasty or vertebroplasty); (c) severe vertebral deformity, fracture, or

other structural abnormality that would preclude a valid DXA-based L1–L4 BMD measurement; or (d) extraspinal medical implants overlying the L1–L4 measurement region (e.g., abdominal aortic stent grafts or vascular grafts).

Comparison of Technological Characteristics

DeepXray Spina has the same general intended use and similar indications for use as the predicate device, Rho (16 Bit, Inc., DEN230023). Both are software-only applications that employ locked AI/ML algorithms trained on DXA reference data to identify patients who may have low BMD, and both generate a single binary output. The principal differences are: (a) DeepXray Spina operates exclusively on the frontal lumbar-spine / KUB view, whereas Rho accepts a broader range of planar radiographs; (b) DeepXray Spina is image-only and does not incorporate demographic variables, whereas Rho does; and (c) DeepXray Spina's binary output is at the WHO osteoporosis threshold ($T \leq -2.5$), whereas Rho's binary output is at the WHO low-bone-mass threshold ($T < -1$). Neither difference alters the intended use or principle of operation, and neither raises new or different questions of safety and effectiveness. A side-by-side comparison of key features is provided in Table 1.

Table 1. Device–Predicate Comparison.

Device	**DeepXray Spina (Subject Device)**	**Rho (DEN230023, Predicate)**
Classification Name & Product Code	Radiology software for opportunistic evaluation of low BMD (SAO)	Radiology software for opportunistic evaluation of low BMD (SAO)
Regulation Number	21 CFR 892.1171	21 CFR 892.1171
Device Class	Class II	Class II (De Novo)
Intended Use	Opportunistic aid to identify patients who may have low BMD from frontal L-spine / KUB radiographs	Opportunistic aid to identify patients who may have low BMD from standard planar radiographs
Intended Patient Population	Adults ≥ 50 years	Adults ≥ 50 years
Input Imaging Region(s)	Frontal lumbar spine or KUB (anatomically matched to L1–L4 reference)	Lumbar spine, thoracic spine, chest, pelvis, knee, or hand/wrist
Algorithm Type	Locked AI/ML; image-only (no demographic inputs)	Locked AI/ML; incorporates demographic inputs
Cleared Device Output	Binary: suspected Low BMD (L1–L4 T-score ≤ -2.5) vs. not suspected (L1–L4 T-score > -2.5)	Binary: suspected low BMD vs. not suspected, at T-score < -1

Nonclinical Performance Data

The following non-clinical performance testing was conducted in support of substantial equivalence, in accordance with 21 CFR 807.92(b)(1):

- Software Verification and Validation Testing: conducted in accordance with the FDA guidance Content of Premarket Submissions for Device Software Functions and IEC 62304:2006/AMD 1:2015. All unit, integration, and system-level tests met pre-specified acceptance criteria. The device is released as a locked AI/ML model.

- Cybersecurity Testing: conducted in accordance with the FDA guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Testing included static code analysis, dynamic code analysis, fuzz testing and penetration testing.

Clinical Performance Data

A retrospective, multi-center clinical performance study was conducted to validate the safety and effectiveness of DeepXray Spina against DXA-derived ground truth. Three independent test datasets, fully disjoint from the algorithm-development dataset, were analyzed: Test Set-1 (Taiwanese Multi-Center Cohort, n = 577), Test Set-2 (Far Eastern Memorial Hospital, Taiwan, n = 159), and Test Set-3 (U.S. Multi-Center Cohort from OneMedNet and Gradient Health, n = 592). The ground truth was the L1–L4 BMD measured by DXA within ± 6 months of the radiograph; T-scores were derived from the NHANES young-adult non-Hispanic white female reference.

Characteristic	Test Set-1 (Taiwanese Multi-Center Cohort)	Test Set-2 (FEMH Cohort)	Test Set-3 (U.S. Multi-Center Cohort)
Number of Subjects (n)	577	159	592
Age: Mean (SD), years	61.61 (11.27)	65.96 (10.99)	67.55 (10.30)
Age: Range, years	(21.39, 96.01)	(31.00, 91.00)	(40.16, 89.83)
Sex: (Female/Male), n (%)	F: 490 (84.92%), M: 87 (15.08%)	F: 129 (81.13%), M: 30 (18.87%)	F: 488 (82.43%), M: 104 (17.57%)
Body Mass Index: Mean (SD), kg/m²	24.02 (3.80)	23.74 (4.30)	27.00 (5.69)
Ethnic Groups: n (%)	Asian: 577 (100.00%)	Asian: 159 (100.00%)	White: 327 (55.24%), Hispanic:120 (20.27%), Black: 78 (13.18%), Asian: 61 (10.30%), unknown: 6 (1.01%)

Characteristic	Test Set-1 (Taiwanese Multi-Center Cohort)	Test Set-2 (FEMH Cohort)	Test Set-3 (U.S. Multi-Center Cohort)
T-score ≤ −2.5 n (%)	149 (25.82%)	63 (39.62%)	101 (17.06%)
−2.5 < T-score < −1 n (%)	219 (37.95%)	60 (37.74%)	213 (35.98%)
T-score ≥ −1 n (%)	209 (36.22%)	36 (22.64%)	278 (46.96%)
#Xray DICOM (Xray paired to DXA)	718	159	749

For the primary classification task (identifying patients with T-score ≤ −2.5, the "Low BMD" screening result), DeepXray Spina demonstrated the following combined performance across all three test sets: AUC = 0.955 (95% CI: 0.942–0.967), sensitivity = 77.0% (95% CI: 72.0%–81.9%), and specificity = 93.6% (95% CI: 92.1%–95.1%).

Table 2. Primary Classification (L1–L4 T-score ≤ −2.5), Intended Use Population, Age ≥ 50

Endpoint	Test Set-1	Test Set-2	Test Set-3	Combined
Scenario 1 – "Report with QC Warning" as reportable result; counted in performance				
#Patients	505	148	566	1,219
AUC	0.961 (0.942, 0.977)	0.968 (0.942, 0.988)	0.942 (0.919, 0.963)	0.955 (0.942, 0.967)
Sensitivity	0.771 (0.699, 0.841)	0.934 (0.857, 0.985)	0.684 (0.581, 0.775)	0.770 (0.720, 0.819)
Specificity	0.954 (0.931, 0.974)	0.874 (0.802, 0.941)	0.931 (0.909, 0.953)	0.936 (0.921, 0.951)
Scenario 2 – "Report with QC Warning" treated as no output; considered as negative result				
#Patients	505	148	566	1,219
AUC	0.961 (0.942, 0.977)	0.968 (0.942, 0.988)	0.942 (0.919, 0.963)	0.955 (0.942, 0.967)
Sensitivity	0.760 (0.688, 0.832)	0.918 (0.836, 0.982)	0.684 (0.581, 0.775)	0.762 (0.712, 0.809)
Specificity	0.954 (0.931, 0.974)	0.874 (0.802, 0.941)	0.933 (0.910, 0.954)	0.937 (0.922, 0.952)

Subgroup analysis

Additional performance metrics were assessed across predefined subgroups, including age, sex, ethnicity, BMI, X-ray equipment manufacturer, and image protocol, to evaluate the consistency and generalizability of the device's performance. These results support the device's effectiveness in reliably identifying high-risk individuals in real-world clinical settings.

Note: Age subgroup analysis includes subjects aged <50 years to account for all enrolled subjects.

Table 3: Classification Performance (T-score ≤ −2.5) by age group

Group	#Patients	#Patients having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
< 50	109	10	0.862 (0.737, 0.993)	0.429 (0.143, 0.875)	0.983 (0.957, 1.000)
50-59	335	59	0.976 (0.962, 0.988)	0.758 (0.648, 0.869)	0.952 (0.925, 0.975)
60-69	466	137	0.948 (0.926, 0.969)	0.784 (0.720, 0.855)	0.937 (0.912, 0.962)
70-79	296	81	0.936 (0.906, 0.963)	0.725 (0.626, 0.830)	0.920 (0.884, 0.952)
>=80	122	26	0.970 (0.937, 0.991)	0.842 (0.687, 0.970)	0.923 (0.865, 0.969)

Note: All subgroup analyses in Table 4 to Table 14 are performed on the Intended Use Population (Age ≥ 50). Subjects aged <50 years are excluded from these analyses.

Table 4: Classification Performance (T-score ≤ −2.5) by Sex

Group	#Patients	#Patients having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
Female	1017	280	0.957 (0.944, 0.970)	0.787 (0.738, 0.836)	0.934 (0.917, 0.952)
Male	202	23	0.924 (0.868, 0.969)	0.571 (0.387, 0.789)	0.942 (0.905, 0.971)

Table 5: Classification Performance (T-score ≤ −2.5) by BMI group

Group	#Patients	#Patients having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
<18.5	37	18	0.974 (0.920, 1.000)	1.000 (1.000, 1.000)	0.750 (0.556, 0.933)
18.5-25	503	156	0.944 (0.918, 0.963)	0.851 (0.794, 0.903)	0.888 (0.851, 0.919)
>=25	450	72	0.971 (0.957, 0.983)	0.655 (0.548, 0.759)	0.972 (0.955, 0.987)
unreported	229	57	0.953 (0.919, 0.978)	0.658 (0.540, 0.780)	0.967 (0.940, 0.988)

Table 6: Classification Performance (T-score ≤ −2.5) by Ethnic group

Group	#Patients	#Patients having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
Asian	712	219	0.956 (0.939, 0.971)	0.809 (0.755, 0.862)	0.936 (0.915, 0.955)
Black	76	9	0.972 (0.919, 1.000)	0.700 (0.333, 1.000)	0.949 (0.892, 0.988)
Hispanic	118	24	0.950 (0.902, 0.987)	0.571 (0.379, 0.786)	0.976 (0.945, 1.000)
White	308	49	0.953 (0.926, 0.975)	0.746 (0.611, 0.860)	0.917 (0.880, 0.950)
Unknown	5	2	0.667 (0.000, 1.000)	0.000 (0.000, 0.000)	1.000 (1.000, 1.000)

* 5 patients with unknown ethnic group are included in the table above

Table 7: Classification Performance (T-score ≤ −2.5) by Xray Manufacturer

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
Canon Inc.	159	189	56	0.985 (0.970, 0.995)	0.857 (0.754, 0.943)	0.962 (0.926, 0.992)
FUJIFILM	362	438	115	0.952 (0.923, 0.974)	0.774 (0.689, 0.853)	0.938 (0.904, 0.966)
GE Healthcare	62	82	9	0.939 (0.862, 0.996)	0.778 (0.411, 1.000)	0.863 (0.771, 0.947)
KONICA MINOLTA	204	231	51	0.955 (0.923, 0.979)	0.765 (0.629, 0.870)	0.928 (0.886, 0.963)
PZMedical	130	147	36	0.981 (0.960, 0.996)	0.833 (0.710, 0.941)	0.964 (0.922, 0.992)
Philips	32	36	6	0.961 (0.857, 1.000)	0.667 (0.000, 1.000)	1.000 (1.000, 1.000)
SAMSUNG	130	171	38	0.934 (0.892, 0.968)	0.711 (0.552, 0.861)	0.895 (0.830, 0.950)
SIEMENS	136	164	39	0.923 (0.866, 0.974)	0.692 (0.545, 0.852)	0.944 (0.904, 0.982)
Others	27	37	7	1.000 (1.000, 1.000)	0.571 (0.200, 1.000)	1.000 (1.000, 1.000)

Table 8: Classification Performance (T-score ≤ −2.5) by Modality type

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
CR	999	1215	301	0.958 (0.943, 0.971)	0.761 (0.703, 0.815)	0.951 (0.935, 0.965)
DX	222	280	56	0.950 (0.921, 0.973)	0.821 (0.702, 0.933)	0.875 (0.824, 0.922)

Table 9: Classification Performance (T-score ≤ −2.5) by DXA Manufacturer

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
GE	1089	1333	328	0.955 (0.940, 0.966)	0.780 (0.729, 0.831)	0.931 (0.914, 0.947)
Hologic	130	162	29	0.961 (0.912, 0.990)	0.655 (0.440, 0.840)	0.970 (0.938, 0.993)

Table 10: Classification Performance (T-score ≤ −2.5) by X-ray Protocol

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
KUB	571	678	166	0.950 (0.931, 0.966)	0.735 (0.667, 0.809)	0.934 (0.910, 0.953)
LSPINE	754	817	191	0.958 (0.939, 0.973)	0.801 (0.736, 0.856)	0.938 (0.917, 0.957)

Table 11: Classification Performance (T-score ≤ −2.5) by X-ray Tube Voltage (kVp)

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
<=80	256	327	77	0.942 (0.908, 0.971)	0.714 (0.604, 0.836)	0.924 (0.887, 0.958)
>80	319	346	96	0.972 (0.958, 0.984)	0.875 (0.807, 0.944)	0.932 (0.900, 0.960)
Unknown	658	822	184	0.950 (0.930, 0.967)	0.739 (0.670, 0.805)	0.942 (0.920, 0.962)

Table 12: Classification Performance (T-score ≤ −2.5) by X-ray Tube Current (mAs)

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
<30	423	500	147	0.946 (0.921, 0.967)	0.810 (0.733, 0.879)	0.907 (0.876, 0.938)
30-40	146	163	36	0.976 (0.953, 0.993)	0.750 (0.588, 0.889)	0.961 (0.921, 0.992)
>40	101	109	20	0.966 (0.929, 0.989)	0.800 (0.619, 0.947)	0.910 (0.844, 0.966)
unknown	584	723	154	0.954 (0.932, 0.972)	0.734 (0.658, 0.810)	0.953 (0.933, 0.971)

Table 13: Classification Performance (T-score ≤ −2.5) by DXA – Xray Interval (days)

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
0	316	347	103	0.959 (0.938, 0.976)	0.806 (0.721, 0.884)	0.947 (0.915, 0.973)
1-60	698	803	175	0.953 (0.932, 0.970)	0.771 (0.700, 0.836)	0.930 (0.907, 0.950)
61-180	276	345	79	0.951 (0.923, 0.973)	0.722 (0.618, 0.821)	0.940 (0.906, 0.970)

Table 14: Classification Performance (T-score ≤ −2.5) by X-ray pixel size (mm)

Group	#Patient	#DICOM	#DICOM having T-score ≤ −2.5 by DXA	AUC	Sensitivity	Specificity
<0.14	266	332	73	0.962 (0.932, 0.984)	0.726 (0.618, 0.829)	0.958 (0.928, 0.982)
0.14-0.16	423	513	128	0.947 (0.925, 0.969)	0.766 (0.690, 0.850)	0.927 (0.898, 0.955)
>0.16	553	650	156	0.956 (0.936, 0.973)	0.795 (0.724, 0.860)	0.931 (0.905, 0.953)

Reproducibility analysis

Reproducibility on 194 cases with repeated acquisitions yielded a coefficient of variation of 3.4% and Cohen's kappa of 0.703–0.706 at the T ≤ −2.5 operating point. There are 118 subjects having 2 X-ray images on the same day, 76 subjects having 2 X-rays on different days (but still paired to the same DXA study).

Table 15: Reproducibility analysis

	X-rays on the same day	X-rays on different days (1-266 day)*
Subject	118	76
% low bone mass (T-score < −1)	55.98%	57.89%
% osteoporosis (T-score ≤ −2.5)	18.64%	26.32%
CV% of Repeated BMD estimation by DeepXray	3.44%	3.38%
Classification for T-score ≤ −2.5		
% agreement	91.53%	90.79%
kappa	0.703	0.706
z statistic	7.815	6.66
p-value	<0.0001	<0.0001
Classification for T-score < −1		
% agreement	88.98%	88.16%
kappa	0.764	0.743
z statistic	12.379	9.349
p-value	<0.0001	<0.0001

***** The same patient having 2 instances of X-ray study on different dates but still paired to the same DXA study. Since the DXA pairing criterion is ± 6 months (180 days), one X-ray study might be before DXA and another after, thus total interval between two X-ray studies could be more than 180 days.

Vertebral ROI Localization

ROI localization was directly validated on Test Set-1 (Asian cohort) against manual reference annotations; all per-vertebra (L1–L4) mean Intersection-over-Union (IoU) values and the overall L-spine ROI bounding-box IoU met the pre-specified acceptance criterion (95% CI lower bound ≥ 0.80). ROI localization was not independently validated with IoU metrics on Test Set-2 and Test Set-3; however, it was indirectly verified across all test sets as an integral intermediate step of the end-to-end AI pipeline, and overall pipeline performance met pre-specified acceptance criteria across all cohorts.

Automated Quality-Control (QC) Function

Evaluated on a dedicated problematic-image set (n = 297; images bearing IFU-excluded conditions against which the QC function serves as a second-tier automated safeguard) and on all clinically acceptable images from Test Sets 1, 2, and 3 (n = 1,626). Two QC performance scenarios are reported. Scenario 1 ("Report with Warning" included as reportable result): QC sensitivity = 76.4% (95% CI: 71.2%–81.1%), QC specificity = 100.0% (95% CI: 99.8%–100.0%). Scenario 2 ("Report with Warning" excluded; treated as no output): QC sensitivity = 93.6% (95% CI: 90.2%–96.1%), QC specificity = 98.2% (95% CI: 97.4%–98.8%).

Substantial Equivalence

DeepXray Spina has the same general intended use (opportunistic identification of patients who may have low BMD), the same intended patient population (adults ≥ 50 years), the same principle of operation (locked AI/ML radiogrammetry with DXA as the training reference), and the same cleared output form (binary classification) as its predicate device, Rho (16 Bit, Inc., DEN230023). The use of the anatomically matched L-spine / KUB input, the image-only inference, and the $T \leq -2.5$ operating point (vs. Rho's $T < -1$) do not alter the intended use and do not raise new or different questions of safety and effectiveness. At the predicate's own operating point ($T < -1$), DeepXray Spina's supporting classification performance (combined AUC = 0.939) is comparable to or exceeds the reported performance of the predicate.

The non-clinical and clinical performance data summarized above demonstrate that DeepXray Spina performs as intended and is as safe and effective as the predicate device for its intended use. The results also fulfill the applicable special controls for product code SAO under 21 CFR 892.1171. DeepXray Spina is therefore substantially equivalent to the predicate device.