



June 15, 2026

CRESCOM Co., Ltd.
Rosa Han
Consultant
Room 801, 8, Seongnam-daero 331beon-gil, Bundang-gu
Seongnam-si, Gyeonggi-do 13558
Republic Of Korea

Re: K253172
Trade/Device Name: MediAI-OA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 17, 2026
Received: May 18, 2026

Dear Rosa Han:

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written over a large, semi-transparent blue watermark of the letters "FDA".

Jessica Lamb, Ph.D.

Assistant Director, Imaging Software 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

Indications for Use

510(k) Number (if known)
K253172

Device Name
MediAI-OA

Indications for Use (Describe)

MediAI-OA is a radiological fully automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based on OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren & Lawrence Grading of standing, fixed-flexion radiographs of the knee.

It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.

The system is to be used by trained professionals including, but not limited to, radiologists, orthopedists, physicians and medical technicians.

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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1. 510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

- **Date** May 08, 2026
- **Applicant / Submitter** CRESCOM Co., Ltd.
Room 801, 8, Seongnam-daero 331beon-gil, Bundang-gu, Seongnam-si,
Gyeonggi-do, 13558, Republic of Korea
Phone +82-70-4820-3843
- **Device Information** Device(Trade) Name: MediAI-OA
Classification Name: Automated Radiological Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
- **Predicate Device** Manufacturer: Alpha Intelligence Manifolds, Inc.
Device(Trade) Name: DeepXray
510(k) Number: K223621
Regulation Name: Medical image management and processing system
Regulatory Number: 21 CFR 892.2050
Regulatory Class: Class II
Product Code: QIH
- **Identification of a Legally Marketed Predicate Device;**
MediAI-OA is substantially equivalent to the DeepXray marketed by Alpha Intelligence Manifolds, Inc.,
510(k) Premarket Notification Number K223621, FDA Product Code QIH.
- **General Description**
MediAI-OA is “Orthopedic image, computer aided detection/ diagnosis software” that automatically
analyzes X-ray images of patients suspected of having osteoarthritis. It assists healthcare providers in
making accurate and consistent diagnoses of knee osteoarthritis by providing information such as KL
(Kellgren-Lawrence) grade, osteophyte grade, sclerosis, and JSN Grade.
- **Indication for Use**

MediAI-OA is a radiological fully automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based on OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren & Lawrence Grading of standing, fixed-flexion radiographs of the knee.

It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.

The system is to be used by trained professionals including, but not limited to, radiologists, orthopedists, physicians and medical technicians.

- **Comparison of Technological Characteristics**

The MediAI-OA and the predicate device DeepXray (K223621) are orthopedic imaging detection and diagnostic support software that assists physicians in diagnosing degenerative arthritis by analyzing knee X-ray images. It displays the KL grade (Kellgren-Lawrence Grade) as well as the presence or absence of JSN, osteophytes, and sclerosis.

Both devices employ deep learning algorithms to analyze input images and the severity of arthritis.

They operate in healthcare facilities and hospitals, are intended for trained professionals including, but not limited to, radiologists, orthopedists, physicians and medical technicians, and are classified under 21 CFR 892.2050, Product Code QIH, Class II.

	Subject Device	Predicate Device (K223621)
Device Name	MediAI-OA	DeepXray
Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software
Product Code	QIH	QIH
Intended Use /Indication for Use	<p>MediAI-OA is a radiological fully automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based on OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren & Lawrence Grading of standing, fixed-flexion radiographs of the knee.</p> <p>It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, radiologists, orthopedists, physicians and medical technicians.</p>	<p>DeepXray is a radiological fully automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the measurement of minimum joint space width; the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based on OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren & Lawrence Grading of standing, fixed-flexion radiographs of the knee.</p> <p>It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, radiologists, orthopedists, physicians and medical technicians.</p>
Anatomical Area	Joint (knee)	Joint (knee)
Image Input	DICOM compliant images in either digitally computed (CR) or directly digital (DX) formats, jpeg, jpg, png.	DICOM compliant images in either digitally computed (CR) or directly digital (DX) formats
Image Processing	Knee detection; Landmark detection; Joint space detection	Knee detection; Landmark detection; Joint space detection
Human Intervention for interpretation	Required	Required
Intended User	Trained professionals	Trained professionals
Output Format	Summary analysis results through the screen, Web report, Markup images and textual report as static images	Web report with quality warning, markup images and editing interface
Output Information	<ul style="list-style-type: none"> - Knee OA status: KL grade 0/1, 2, 3 or 4 - JSN status: Absent/Present - Osteophyte status: Absent/Present - Sclerosis status: Absent/Present 	<ul style="list-style-type: none"> - Knee OA status: KL grade ≥ 2 or ≤ 1 - JSN status: Absent/Present - Osteophyte status: Absent/Present - Sclerosis status: Absent/Present
Runs on Server	Yes	Yes

- **Brief Summary of Non-Clinical Tests and Results**

The MediAI-OA complies with the following international and FDA-recognized consensus standards list in the below table.

Recognition No.	Standard No.	Title of Standard	Remark
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes	
5-129	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to med	
5-125	ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical device	
13-131	SW96:2023	Standard for medical device security - Security risk management for device manufacturers	
13-122	81001-5-1 Edition 1.0 2021-12	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle	
13-83	TIR57:2016	Principles for medical device security - Risk management.	

And MediAI-OA comply with the FDA guidance documents listed in the below table.

Title of Guidance Document	Issue Date
Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	July 28, 2014
Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff	June 14, 2023
Off-The-Shelf Software Use in Medical Devices	August 11, 2023
Cybersecurity in Medical Devices Quality System Considerations and Content of Premarket Submissions	February 3, 2026

The risk analysis was completed and risk controls were implemented to mitigate identified hazards.

- Brief Summary of Performance Tests and Results**

CRESCOM conducted an independent clinical performance test of MediAI-OA. The test dataset was configured as follows. Site-based Data Partitioning To prevent data leakage and ensure the clinical validity of the algorithm, the study datasets were strictly partitioned by Clinical Site IDs rather than by individual patient randomization. The OAI protocol identifies multiple independent recruitment centers distributed across different geographic locations. Each site maintained its own participant pool and initial data files. The performance test was conducted using data from sites that were completely separate from those used for training and validation. The X-ray equipment manufacturers used for the images included Agfa, Fujifilm, GE and etc. (None of the cases used in this study were utilized for training or validation of the MediAI-OA model.)

Characteristics	Category		Training & Validation Set		Independent Test Set	
Gender	Female		2,156 (59.5%)		648 (55.2%)	
	Male		1,467 (40.5%)		525 (44.8%)	
Age (Years)	Age \geq 60		1,904 (52.6%)		681 (58.0%)	
	Age < 60		1,719 (47.4%)		492 (42.0%)	
Race	Other Non-white		70 (2.0%)		12 (1.0%)	
	White		2,808 (77.5%)		982 (83.8%)	
	Black or African American		709 (19.6%)		165 (14.0%)	
	Asian		31 (0.8%)		14 (1.2%)	
	Unknown or not reported		5 (0.1%)		0 (0.0%)	
Total Subjects			3,623		1,173	
KL	KL 0/1	KL < 2	22,253		6,598	
	KL 2	KL \geq 2	10,212	18,912	2,799	4,785
	KL 3		5,813		1,574	
	KL 4		2,887		412	
Total Knees			41,165		11,383	
JSN	OARSI Grade 0		53,441		17,903	
	OARSI Grade \geq 1		13,803		4,861	
Total JSN			67,244		22,764	
Osteophyte	OARSI Grade 0		20,138		6,050	
	OARSI Grade \geq 1		20,325		5,056	
Total Osteophyte			40,493		11,106	
Sclerosis	Absent		28,357		8,164	
	Present		4,326		2,822	
Total Sclerosis			32,683		10,986	

Characteristics	Category	Training & Validation Set	Independent Test Set
Modality	CR	10,219	5,444
	DX	2,935	246
	RG	3,657	0
	Unknown	0	1
X-ray Manufacturer	Agfa	3,826	4,600
	Fujifilm	2,577	870
	GE	2,946	220
	Konica-Minolta	2,008	0
	Pilips	35	0
	Siemens	302	0
	Swissray	3,468	0
	Others (Not reported)	1,649	1
Total DICOM		16,811	5,691
Visiting Timepoint (Follow-up Period)	Baseline	11,492	1,114
	12 months	3,097	1,049
	24 months	2,917	962
	36 months	2,763	918
	48 months	2,610	872
	72 months	1,031	380
	96 months	1,061	396

All annotations used as the reference standard were manually performed by qualified annotators who were rigorously trained in accordance with the OAI (Osteoarthritis Initiative) Standardized Reading Protocol. These annotations were used exclusively as ground truth during the model development and internal validation phases.

During the performance evaluation (inference) stage, the algorithm automatically generates all required diagnostic outputs, such as KL grade and sclerosis detection, without any manual intervention or prior knowledge of the reference labels. Furthermore, to ensure the objectivity of the performance evaluation, the datasets for training, validation, and testing were strictly separated, thereby eliminating any risk of data leakage.

The clinical performance test was conducted by comparing the software's osteoarthritis assessment results with the reference standard derived from the OAI dataset, using sensitivity and specificity as evaluation metrics. As a result, MediAI-OA was confirmed to meet all of the predefined performance criteria described below.

- For KL grade classification, both sensitivity and specificity across all grades met performance targets comparable to those reported in previously conducted studies. In particular, for the detection of KL grade ≥ 2 , the sensitivity was 0.876 (95% CI: 0.866–0.885) and the specificity was 0.865 (95% CI: 0.856–0.873). The lower bounds of the confidence intervals exceeded the predefined acceptance criteria, indicating strong discriminatory performance between normal and osteoarthritis cases.

Additionally, the sensitivity by KL grade was 0.865 (95% CI: 0.856–0.873) for grades 0 & 1, 0.717 (95% CI: 0.700–0.734) for grade 2, 0.750 (95% CI: 0.728–0.770) for grade 3, and 0.905 (95% CI: 0.873–0.930) for grade 4. The specificity was 0.876 (95% CI: 0.866–0.885) for grades 0 & 1, 0.862 (95% CI: 0.854–0.869) for grade 2, 0.972 (95% CI: 0.969–0.975) for grade 3, and 0.995 (95% CI: 0.993–0.996) for grade 4, demonstrating excellent discriminatory performance in distinguishing normal subjects from patients with osteoarthritis.

- For joint space narrowing (JSN) \geq OARSI grade 1, the sensitivity and specificity were 0.880 (95% CI: 0.871–0.889) and 0.864 (95% CI: 0.860–0.869), respectively, demonstrating consistent and accurate detection of structural changes.

- For osteophyte detection \geq OARSI grade 1, the sensitivity was 0.897 (95% CI: 0.888–0.905) and the specificity was 0.823 (95% CI: 0.813–0.833), indicating robust performance across varying severity levels.

- For sclerosis classification (presence/absence), the sensitivity and specificity were 0.88 (95% CI: 0.87–0.89) and 0.90 (95% CI: 0.89–0.90), respectively, demonstrating a high level of agreement with the reference standard.

Overall, MediAI-OA demonstrated accurate and reliable assessment of radiographic features of knee osteoarthritis, with clinical performance comparable to results obtained from annotations manually performed by qualified annotators who were rigorously trained in accordance with the OAI (Osteoarthritis Initiative) Standardized Reading Protocol.

- **Conclusion**

Based on the non-clinical and clinical evidence, MediAI-OA is substantially equivalent to the legally marketed predicate device in terms of safety, effectiveness, and performance. The device introduces no new risks and demonstrates comparable functionality in aiding medical professionals in the assessment of radiographic features of knee osteoarthritis, supporting its suitability for regulatory clearance.