Rosa Han
Official Correspondent
801 Kinstower, 8 Seongnam-daero 331beon-gil
Seongnam-si, Gyeonggi-do 13558
Korea, South

December 18, 2025

Re: K250914
Trade/Device Name: MediAI-BA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 7, 2025
Received: November 7, 2025

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 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,

Jessica Lamb, Ph.D
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250914

Device Name
MediAI-BA

Indications for Use *(Describe)*
The MediAI-BA is designed to view and quantify bone age from 2D Posterior Anterior (PA) view of left-hand radiographs using deep learning techniques to aid in the analysis of bone age assessment of patients between 2 to 18 years old for pediatric radiologists. The results should not be relied upon alone by pediatric radiologists to make diagnostic decisions. The images shall be with left hand and wrist fully visible within the field of view, and shall be without any major bone destruction, deformity, fracture, excessive motion, or other major artifacts.

Limitations:
– This software is not intended for use in patients with growth disorders caused by congenital anomalies (e.g., Down syndrome, Noonan syndrome, congenital adrenal hyperplasia, methylmalonic acidemia, skeletal dysplasia, chronic renal disease, or prior long-term steroid exposure), as these conditions may cause complex skeletal changes beyond bone maturation.

– Images showing anatomical variations or notable abnormalities (e.g., bone tumors, sequelae of fractures, or congenital deformities) in the region required for interpretation are excluded from the intended use.

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.

510(k) Summary

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

- **Date** March 18, 2025

- **Submitter**
  CRESCOM Co., Ltd.
  801 Kinstower, 8 Seongnam-daero 331beon-gil, Seongnam-si, Gyeonggi-do, 13558 Republic of Korea

- **Contact Person**
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  RA Specialist
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- **Device Information**
  Device(Trade) Name: MediAI-BA
  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: Ever Fortune.AI Co., Ltd.
  Trade/Device Name: EFAI BAPXR
  510(k) Number: K234042
  Regulation Name: Medical image management and processing system
  Regulatory Number: 210 CFR 892.2050
  Regulatory Class: Class II
  Product Code: QIH

- **Identification of a Legally Marketed Predicate Device;**
  MediAI-BA is substantially equivalent to the EFAI BAPXR marketed by Ever Fortune.AI Co., Ltd., 510(k) Premarket Notification Number K234042, FDA Product Code QIH.

- **General Description**
  This AI-based software utilizes an internal algorithm that integrates global skeletal maturity features extracted from the whole hand radiograph with local skeletal maturity features derived from key Regions of Interest (ROIs). By synthesizing these skeletal maturity features, the software determines the accurate final bone age.

  MediAI-BA provides an optional heatmap visualization that highlights regions contributing to the AI model output. The heatmap is intended only as supplementary, qualitative information to illustrate internal AI operations and is not intended for clinical interpretation, growth plate localization, or independent bone age assessment.

  The confidence score graph is an internal model visualization intended only to illustrate the relative sharpness of the model's output distribution. It is not calibrated to clinical likelihood, has not been clinically validated, and is not intended to support diagnostic decisions or selection of a specific bone

age.

- **Indication for Use**

The MediAI-BA is designed to view and quantify bone age from 2D Posterior Anterior (PA) view of left-hand radiographs using deep learning techniques to aid in the analysis of bone age assessment of patients between 2 to 18 years old for pediatric radiologists. The results should not be relied upon alone by pediatric radiologists to make diagnostic decisions. The images shall be with left hand and wrist fully visible within the field of view, and shall be without any major bone destruction, deformity, fracture, excessive motion, or other major artifacts.

Limitations:
– This software is not intended for use in patients with growth disorders caused by congenital anomalies (e.g., Down syndrome, Noonan syndrome, congenital adrenal hyperplasia, methylmalonic acidemia, skeletal dysplasia, chronic renal disease, or prior long-term steroid exposure), as these conditions may cause complex skeletal changes beyond bone maturation.

– Images showing anatomical variations or notable abnormalities (e.g., bone tumors, sequelae of fractures, or congenital deformities) in the region required for interpretation are excluded from the intended use.

- **Comparison of Technological Characteristics**

	Subject Device	**Predicate Device (K234042)**
Device(Trade) Name	MediAI-BA	EFAI BAPXR
Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software
Product Code	QIH	QIH
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Regulatory Class	Class II	Class II
Intended Use/Indication for Use	The MediAI-BA is designed to view and quantify bone age from 2D Posterior Anterior (PA) view of left-hand radiographs using deep learning techniques to aid in the analysis of bone age assessment of patients between 2 to 18 years old for pediatric radiologists. The results should not be relied upon alone by pediatric radiologists to make diagnostic decisions. The images shall be with left hand and wrist fully visible within the field of view, and shall be without any major bone destruction, deformity, fracture, excessive motion, or other major artifacts. Limitations: – This software is not intended for use in patients with growth disorders caused by congenital anomalies (e.g.,	EFAI BONESUITE XR BONE AGE PRO ASSESSMENT SYSTEM (EFAI BAPXR) is designed to view and quantify bone age from 2D Posterior Anterior (PA) view of left-hand radiographs using deep learning techniques to aid in the analysis of bone age assessment of patients between 2 to 16 years old for pediatric radiologists. The results should not be relied upon alone by pediatric radiologists to make diagnostic decisions. The images shall be with left hand and wrist fully visible within the field of view, and shall be without any major bone destruction, deformity, fracture, excessive motion, or other major artifacts.

	Down syndrome, Noonan syndrome, congenital adrenal hyperplasia, methylmalonic acidemia, skeletal dysplasia, chronic renal disease, or prior long-term steroid exposure), as these conditions may cause complex skeletal changes beyond bone maturation. – Images showing anatomical variations or notable abnormalities (e.g., bone tumors, sequelae of fractures, or congenital deformities) in the region required for interpretation are excluded from the intended use.	
Environment of Use	Healthcare facility/Hospital	Healthcare facility/Hospital
Intended User	Pediatric radiologist	Pediatric radiologist
Clinical Condition	Bone age assessment	Bone age assessment
Image Input	Complies with DICOM standard	Complies with DICOM standard
Scan Type	X-ray	X-ray
Anatomical Area	Left hand and wrist	Left hand and wrist
Image Display Mode	Static	Static
Artificial Intelligence Algorithm	Yes	Yes
Image Navigation and Manipulation Tools	No	No
2D Image Review	No	No
Manual Landmark Placement	No	No
Semi-automatic Landmark Placement	No	No
Quantitative Analysis	Bone age assessment (years)	Bone age assessment (years)
Report Creation	Yes	No

The MediAI-BA and the predicate device EFAI BAPXR (K234042) are both AI-based automated radiological image processing software designed to assist pediatric radiologists in bone age assessment using 2D Posterior-Anterior (PA) X-ray images of the left hand and wrist.

Both devices employ deep learning algorithms to analyze input images and generate bone age estimates. They operate in healthcare facilities and hospitals, are intended for pediatric radiologists,

and are classified under 21 CFR 892.2050, Product Code QIH, Class II.

- **Brief Summary of Performance Testing**

CRESCOM conducted an independent performance evaluation study of MediAI-BA.
The test dataset consisted of 600 cases aged 2–18 years, collected from five sites across multiple states and multiple clinical organizations in the United States. The study population included 50.0% males and 50.0% females, and the racial/ethnic composition comprised White, Hispanic, Black, Asian & Pacific Islander, among others.

The X-ray scanner manufacturers used for the images included Samsung Electronics, Carestream Health, Kodak, Siemens, and Konica Minolta. (None of the cases used in this study were utilized for training or development of the MediAI-BA model.)

By comparing the software's bone age analysis results with the ground truth established by four evaluators, MediAI-BA was confirmed to meet all of the predefined performance criteria described below.

- In the Deming regression analysis, the slope was 1.000 (95% CI: 0.989–1.002) and the intercept was 0.08 (95% CI: −0.004–0.158), which is close to zero. The confidence intervals included 1 for the slope and 0 for the intercept, indicating no significant proportional or systematic bias between the software and the reference standard measurements.
- In the Bland–Altman analysis, the 95% limits of agreement for bone age assessment between the ground truth and MediAI-BA outputs ranged from −0.66 (−1.96 SD) to 0.71 (+1.96 SD), demonstrating high consistency and agreement.
- When the frequency distribution (histogram) of differences between MediAI-BA bone age measurements and the reference standard was analyzed with a bin width of 0.25 years, the mean difference was 0.026 years and the standard deviation was 0.3505 years, with most cases clustered near zero. Additionally, 89% of all cases demonstrated a difference of less than 0.5 years between the ground truth values and the software output.

Therefore, the automatic AI-based bone age assessment software, MediAI-BA, demonstrated performance comparable to bone age readings obtained by human evaluators using the GP atlas method.

We evaluated the consistency and accuracy of the heatmaps provided as visual evidence for MediAI-BA.

Consistency tests showed that most of the 30 evaluation cases met the predefined criterion (SSIM $\geq$ 0.85). All cases met the criteria under brightness adjustment and Gaussian noise conditions, and all five cases under rotation conditions also met the criteria. While some cases exhibited low SSIM scores under extreme conditions, such situations are considered highly unlikely to occur in real-world clinical imaging settings.
Accuracy tests revealed that bone age changes were observed in 27 of the 30 cases when the highlighted region of the heatmap was masked. In the remaining three cases, similar bone age values were observed in other regions even when a specific region was masked, indicating that masking did not significantly impact the evaluation results.

In conclusion, MediAI-BA's heatmap function demonstrated reliable visual consistency and accuracy across most test cases. Therefore, heatmaps can be used as a supplementary reference for understanding the interpretation of AI analysis results.

- **Conclusion**
  Based on the nonclinical and clinical evidence, MediAI-BA 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 and optimized workflow efficiency in bone age assessment, supporting its suitability for regulatory clearance.