Ever Fortune.AI Co., Ltd.
Ti-Hao Wang
Chief Technology Officer
Rm. D, 8F. No. 573, Sec. 2 Taiwan Blvd. West Dist.
Taichung City, 403020
Taiwan

June 7, 2024

Re: K234042
Trade/Device Name: EFAI Bonesuite XR Bone Age Pro Assessment System (BAP-XR-100)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 24, 2024
Received: May 24, 2024

Dear Ti-Hao Wang:

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.

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
Assistant Director
Imaging Software 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.

Submission Number *(if known)*

K234042

Device Name

EFAI BONESUITE XR BONE AGE PRO ASSESSMENT SYSTEM (BAP-XR-100)

Indications for Use *(Describe)*

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.

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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510(k) Summary

1. General Information

510(k) Sponsor	Ever Fortune.AI Co., Ltd.
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Applicant	Joseph Chang
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Date Prepared	October, 2023

2. Proposed Device

Proprietary Name	EFAI Bonesuite XR Bone Age Pro Assessment System (BAP-XR-100)
Common Name	EFAI BAPXR
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QIH
Regulatory Class	II

3. Predicate Device

Proprietary Name	Medo Aria
Premarket Notification	K200356

Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QIH
Regulatory Class	II

4. Device Description

The device is a software designed to aid the quantification of bone age for patients between 2 to 16 years old. The software uses deep learning techniques to analyze posterior-anterior (PA) radiographs of the left-hand according to the Greulich-Pyle (GP) method.

Intended User Population

The intended users of EFAI BAPXR are pediatric radiologists.

When a clinician accesses the patient radiographs in a picture archiving and communication system (PACS) client or a workstation, both the EFAI BAPXR quantification and the original unaltered radiographs are available in the same patient study, allowing for concurrent reading.

EFAI BAPXR is an adjunct tool and is not intended to replace a clinician's review of the radiograph or his or her clinical judgment. Clinicians must not use the software generated output as the primary interpretation.

Intended Patient Population

The target population of the device are patients between 2 and 16 years old that require a bone age assessment.

Description of output

The algorithm outputs a standard JSON message, to ensure consistent interpretation and simple integration across systems. The result contains structured information in regards to the estimated bone age in years and the data can be transferred and processed by RIS/HIS/PACS and other workstations.

5. Intended Use

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.

6. Comparison of Technological Characteristics with Predicate Device

Feature/ Function	**Proposed Device:** *EFAI BAPXR (K234042)*	**Predicate Device:** *Medo Aria (K200356)*
Intended Use/Indication for Use	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.	MEDO ARIA is designed to view and quantify ultrasound image data using machine learning techniques to aid trained medical professionals in diagnosis of developmental dysplasia of the hip (DDH). The device is intended to be used on neonates and infants, aged 0 to 12 months.
Environment of Use	Healthcare facility/Hospital	Healthcare facility/Hospital
Intended user	Pediatric radiologist	Radiologist
Clinical condition	Bone age assessment	developmental dysplasia of the hip (DDH)
Image Input	Complies with DICOM standard	Complies with DICOM standard
Scan Type	X-ray	2D and 3D Ultrasound
Body Part	Left hand and wrist	Hip

Image display mode	Static	Static
Artificial Intelligence Algorithm	Yes	Yes
Image navigation and manipulation tools	No	Adjust image brightness and contrast, slice-scroll, pane layout, reset
2D image review	No	Yes, capable of reviewing all frames of multi-frame (multi-slice) image
Manual landmark placement	No	Yes
Semi-automatic landmark placement	No	Yes, user-modifiable
Quantitative analysis	Bone age assessment (years)	• Angle (alpha angle) • Distance ratio (coverage)
Report creation	No	Yes

7. Performance Data

Performance of the EFAI BAPXR has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with *IEC 62304:2006/A1:2016 - Medical device software – Software life cycle processes,* in addition to the FDA Guidance documents, *"Content of Premarket Submissions for Device Software Functions"* and *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."*

To establish the performance of EFAI BAPXR, the performance was validated by nonclinical and clinical tests.

Nonclinical Tests

During the process of model development, a total of 26,222 cases were retrospectively collected from Taiwan and the United States (U.S.). These cases were subsequently divided into training and testing datasets, consisting of 23,578 and 2,644 cases, respectively.

An internal validation test was conducted to assess the performance of the EFAI BAPXR. Ground-truthing was the average of the bone age assessment independently done by three board-certified radiologists.

Overall, the Deming regression analysis result showed a good correlation between GT and EFAI BAPXR's output. The intercept of the regression line was -0.06 with a 95% CI of [-0.09, -0.03]

and the slope was 1.00 with a 95% CI of [1.00, 1.01]. By confirming that the CIs of both measures fall within the highest acceptable bias.

Clinical Tests

EFAI conducted a standalone performance study with the proposed device EFAI BAPXR with a pre-determined primary endpoint and performance goal to evaluate the software's performance on left-hand X-ray images in PA view. The test data comprised 600 cases aged 2-16 years, acquired from 27 locations across multiple states and multiple clinical organizations in the United States. The study population contained 50.0% males and 50.0% females, with a mean chronological age of cases was 9.2 years old and 120 cases in each three-year age interval.The race or ethnicities of cases include White, Hispanic, Black, Asian, Multiple, etc. The X-Ray scanner manufacturers of images include Samsung Electronics, Carestream Health, Kodak, GE Healthcare, Siemens, Konica Minolta, etc. None of the cases was used as part of the EFAI BAPXR model training or development.

The study design measured the performance of EFAI BAPXR against the ground truth (GT) from four U.S. board-certified expert radiologists. As shown in the following figure (***Figure A***) for the ground truthing workflow, the ground truthing was generated through the truthing process based on the current standard of care, with the addition of multiple checkpoints to ensure consistency and consensus among all readers reviewing the radiographs when comparing them to the Greulich-Pyle Atlas.

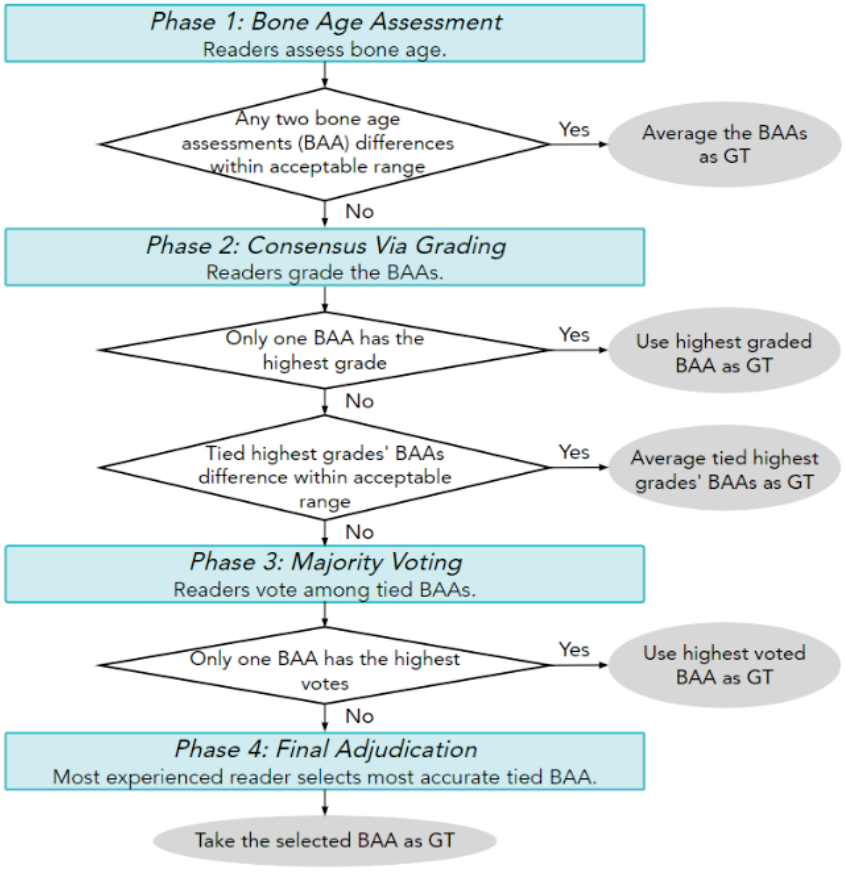

Figure A. Ground Truthing Workflow

The primary endpoint was the intercept and slope of a Deming regression between GT and EFAI BAPXR's output. The acceptance criteria were met if both the intercept and slope of the regression line had fallen within the range of the highest acceptable bias.

The observed results of the standalone performance validation study demonstrated that EFAI BAPXR can provide bone age assessments with satisfactory results including over 88% of the cases with a difference less than 0.5 years between GT and EFAI BAPXR's output. The intercept of the Deming regression result was -0.07 with a 95% Confidence Interval (95% CI) of [-0.13, -0.01] and slope of 1.00 with a 95% CI of [0.99, 1.00]. Overall, the device performance met the performance goal compared with the GT, thus reaching the primary endpoint. In addition, as shown in the following Bland-Altman plot (***Figure B***), the 95% limits of agreement (red solid lines) for bone age assessment between GT and EFAI BAPXR's output ranged from -0.517 to 0.743 (with corresponding CIs in gray dashed lines), indicating high consistency.

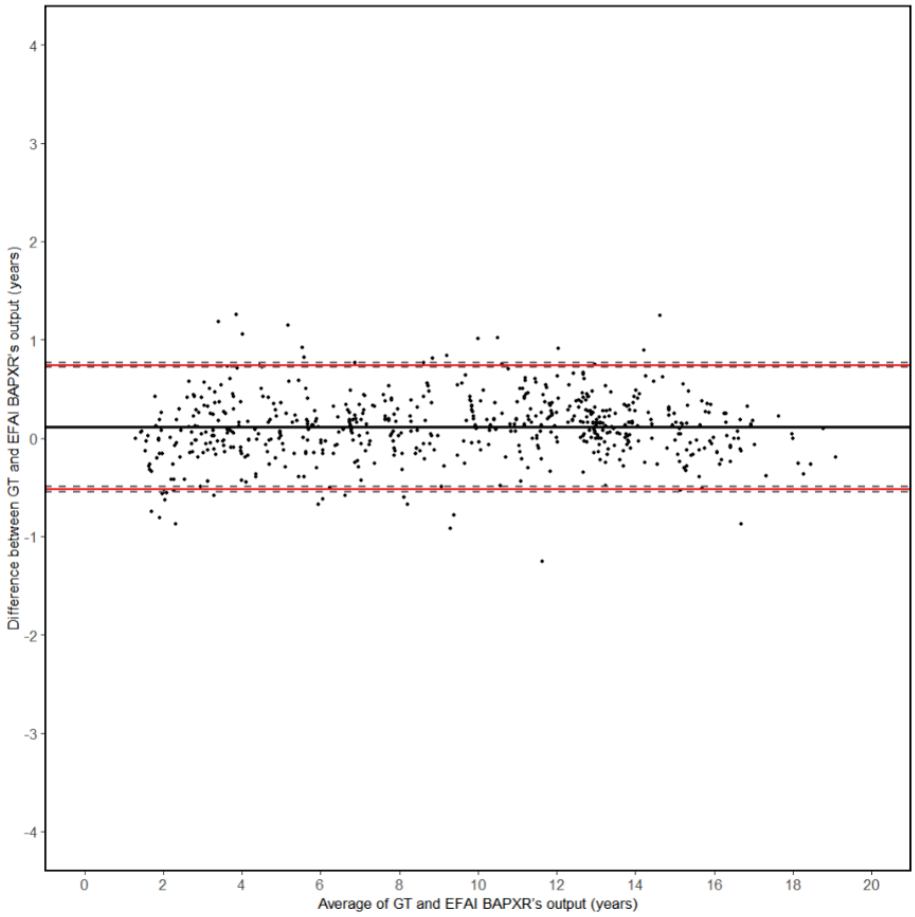

Figure B. Bland-Altman Plot of the EFAI BAPXR

As shown in the table below, we also evaluated the performance of EFAI BAPXR in various clinical subgroups to see if these factors systematically affect the device performance, including gender, age, race or ethnicity, clinical organization, X-ray manufacturer, input image with radiologic findings (including epiphyseal, finger, carpal/ metacarpal, radius/ ulna, others, and multiple), and image quality issues (including poor image quality, poor position, foreign body, artifact, and multiple).

Table. Subgrouping Analysis Results of EFAI BAPXR

	Intercept (95% CI)	Slope (95% CI)
Gender		
Female	0.01 (-0.07, 0.09)	0.99 (0.98, 1.00)
Male	-0.14 (-0.23, -0.04)	1.00 (0.99, 1.01)
Age		
Pre-puberty	0.03 (-0.07, 0.13)	0.98 (0.96, 0.99)
Early & Mid-puberty	-0.06 (-0.25, 0.13)	0.99 (0.98, 1.01)
Late-puberty	-1.10 (-1.46, -0.74)	1.07 (1.04, 1.09)
Race or Ethnicity		
White	-0.05 (-0.14, 0.04)	0.99 (0.99, 1.00)
Hispanic	0.05 (-0.12, 0.22)	0.98 (0.97, 1.00)
Black or African	-0.17 (-0.55, 0.20)	1.01 (0.98, 1.04)
Asian	-0.12 (-0.28, 0.04)	0.99 (0.98, 1.01)
Multiple	-0.19 (-0.36, -0.01)	1.00 (0.98, 1.02)
Other Races or Ethnicities	-0.07 (-0.31, 0.17)	0.99 (0.97, 1.01)
Clinical Organization		
Org A	0.12 (-0.13, 0.37)	0.97 (0.94, 1.01)
Org B	-0.24 (-0.69, 0.21)	1.01 (0.97, 1.05)
Org C	-0.11 (-0.24, 0.02)	0.99 (0.98, 1.00)
Org D	-0.07 (-0.15, 0.01)	1.00 (0.99, 1.01)
X-ray Manufacturer		
Samsung Electronics	-0.17 (-0.33, -0.01)	1.00 (0.99, 1.01)
Carestream Health	-0.03 (-0.16, 0.10)	0.99 (0.98, 1.00)
Kodak	-0.17 (-0.28, -0.07)	1.01 (1.00, 1.02)
GE Healthcare	0.01 (-0.23, 0.25)	0.99 (0.96, 1.01)
Siemens	0.05 (-0.10, 0.20)	1.00 (0.99, 1.02)
Konica Minolta	0.12 (-0.10, 0.35)	0.97 (0.94, 1.00)
Other Manufacturers	0.05 (-0.29, 0.39)	0.99 (0.96, 1.02)
Cases with Radiologic Findings	-0.03 (-0.14, 0.08)	0.99 (0.98, 1.01)
Cases with Image Quality Findings	-0.04 (-0.19, 0.11)	1.00 (0.98, 1.01)

Pre-puberty: female ages [2 - 7) & male ages [2 - 9).
Early & Mid-puberty: female ages [7 - 13) & male ages [9 - 14).
Late-puberty: female ages [13 - 16] & male ages [14 - 16].
Other races or ethnicities include American Indian/Alaska Native, Pacific Islander/Native Hawaiian, others and unreported.
Other manufacturers include Fujifilm Corporation, Canon Inc., and Hologic, Inc..

Overall, we found the device performs consistently and reliably under these circumstances, this concludes the performance demonstrated that the EFAI BAPXR device is as safe and effective as the predicate device Medo Aria.

8. Safety & Effectiveness

EFAI BAPXR has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with ISO 14971:2019 Medical devices — Application of risk management to medical devices. The EFAI BAPXR performance has been validated using retrospective data from case data and through the use of Reader comparison analysis.

9. Substantial Equivalence

The EFAI BAPXR has minor differences compared to the predicate device. These differences are related to the Intended Use and to the Quantitative Analysis features.

The Medo Aria predicate is intended to quantify ultrasound images to support diagnosis of development dysplasia of the hip (DDH) based on Graf. The EFAI BAPXR is intended to quantify bone age based on an image atlas. Although the intended uses are different, the principle of operation is the same as both devices use artificial intelligence algorithms to view and quantify radiograph images and provide results based on an established reference or standard. Both devices have similar risks and are mitigated by similar special controls. Both devices rely on labeling and clinical performance testing as mitigations to address risks related to the use of the devices. Therefore, although the intended uses are not exactly the same, the risks and technology used by both devices are the same and are mitigated similarly and thus the proposed device does not raise new questions of safety or efficacy as no new risks are introduced.

The predicate device consists of a user interface in which end users are able to interact with images using typical image navigation and manipulation tools, including landmark placement. The proposed device does not consist of a typical user interface which allows users to interact with images using typical image navigation and manipulation tools, including landmark placement. However, this difference does not raise new questions of safety or efficacy and does not add new or significant risk to the device as the differences are workflow related and the end users are able to still access the original image to interpret the image according to standard practices.

10. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, the EFAI BAPXR raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.