



September 22, 2026

Visiana ApS
% Janice Hogan
Partner
Hogan Lovells Cadwalader US LLP
1735 Market St., Floor 23
Philadelphia, Pennsylvania 19103

Re: K262390

Trade/Device Name: BoneXpert
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 13, 2026
Received: July 13, 2026

Dear Janice Hogan:

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 in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

Jessica Lamb, PhD
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262390

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Please provide the device trade name(s).

?

BoneExpert

Please provide your Indications for Use below.

?

BoneXpert is designed to view and quantify bone age from 2D Posterior Anterior (PA) hand radiographs using machine learning techniques to aid in the analysis of bone age assessment of patients between 2-21 years old for pediatric radiologists. The results should not be relied upon alone to make diagnostic decisions. The images shall be without any major bone deformity and without excessive image postprocessing (edge enhancement).

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☐ Adults (22 years old and greater)

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510(k) SUMMARY

Visiana ApS's BoneXpert Software

Applicant Name and Contact Person

Visiana ApS
Fremtidsvej 1
2970 Hørsholm
Denmark
Phone: +45 2144 7087
Email: support@visiana.com
Contact Person: Hans Henrik Thodberg

Date Prepared: July 13, 2026

Name of Device BoneXpert

Name/Address of Sponsor

Visiana ApS
Fremtidsvej 1
2970 Hørsholm
Denmark

Common Name: Automated Radiological Image Processing Software

Classification Name: Medical image management and processing system

Regulation Number: 21 CFR 892.2050

Product Code: QIH

Predicate Devices

EFAI Bonesuite XR Bone Age Pro Assessment System - K234042.

Intended Use / Indications for Use

BoneXpert is designed to view and quantify bone age from 2D Posterior Anterior (PA) hand radiographs using machine learning techniques to aid in the analysis of bone age assessment of patients between 2-21 years old for pediatric radiologists. The results should not be relied upon alone to make diagnostic decisions. The images shall be without any major bone deformity and without excessive image postprocessing (edge enhancement).

Device Description

BoneXpert is DICOM image processing software that analyzes pediatric hand radiographs. The software is installed on a Windows PC or Windows virtual machine within the hospital network and is configured as a DICOM destination. Images may be sent from PACS or directly from the X-ray

modality. BoneXpert analyzes each image and returns an annotated DICOM image into the same study in PACS for review by the radiologist.

BoneXpert determines bone age according to the Greulich-Pyle method and displays which bones were used for the assessment. The result box includes chronological age, patient sex, Greulich-Pyle bone age and carpal bone age (for younger children). The result box may also include bone age standard deviation scores, bone age standard deviation, and percent mature height.

Substantial Equivalence

Indications for Use Comparison

BoneXpert and the predicate device, EFAI Bonesuite XR Bone Age Pro Assessment System (BAP-XR-100), have the same intended use and similar indications for use. Both devices quantify bone age from 2D hand radiographs in pediatric patients and are intended to aid radiologists in bone age assessment without replacing clinical judgment.

The differences in age range, algorithm type, and hand laterality do not change the intended use. These differences reflect routine clinical use and device-specific implementation, and do not raise different questions of safety or effectiveness.

Thus, BoneXpert has the same intended use as its predicate device.

Technological Comparison

BoneXpert and the predicate have similar technological characteristics. Both are software-only devices that analyze pediatric posterior-anterior hand radiographs according to the Greulich-Pyle method to provide an estimated bone age.

- Predicate device uses deep learning-based algorithms, while the subject device uses machine learning-based algorithms to analyze the input images.
- Predicate device accepts images of the left hand only, while the subject device can accept images of either left or right hands.
- Subject device provides an annotated image that displays the contours of the bones and their individual scores that contributed to the primary average bone age estimation output, while the predicate provides a JSON message with structured information on estimated bone age.
- Subject device provides secondary interpretative outputs, such as carpal bone age, bone age standard deviation, percent mature height, and bone age standard deviation scores.
- Subject device includes an image validation step to ensure analyzed images are anatomically appropriate and of adequate image quality.

The devices differ in certain technological characteristics, including the underlying algorithm approach, accepted hand laterality, output format, availability of secondary outputs, and BoneXpert's image validation step. These differences do not alter the clinical workflow or the fundamental information provided to the radiologist.

The secondary outputs and annotated image provide supplementary context for interpretation of the primary bone age result. They do not introduce a new clinical application or replace radiologist review.

Clinical and bench testing support that BoneXpert performs as intended and that these differences do not raise different questions of safety or effectiveness.

Principles of Operation

Both devices operate within the standard radiology workflow, provide an estimated bone age based on an established clinical standard, and require radiologist review of the device output.

Non-Clinical and/or Clinical Tests Summary

Clinical and bench testing was conducted to demonstrate BoneXpert performance. The primary clinical evidence is the Stanford multicenter study, which evaluated 1,285 images from five U.S. clinical sites and assessed BoneXpert performance using interchangeability and model-based variance-decomposition analyses.

BoneXpert demonstrated a lower RMSE than a single manual rater when compared against a three-rater reference, fewer large deviations, and estimated true accuracy comparable to or better than human rater variability.

Although the subject and predicate performance studies used different statistical methods, both demonstrate agreement between device output and expert radiologist ground truth established using the Greulich-Pyle method.

Additional evidence provided includes:

- Supplementary Accuracy Studies: summary of independent, peer-reviewed studies comparing BoneXpert with at least one other automated bone age method.
- Validation of carpal bone age.
- Evaluation of whether the self-validation mechanism appropriately prevents bone age output when the input image is outside the device's valid scope.
- Efficiency: evaluation of BoneXpert's self-validation rejection rate.
- Precision Study: demonstration of high repeatability of BoneXpert's GP bone age output across longitudinal measurements.
- Reference Curve Study: construction of bone age reference curves and bone age standard deviation score interpretation.
- Additional bench studies evaluated BoneXpert's robustness to image transformations, reproducibility under clinically relevant image-quality variation, performance with atypical image features or artifacts, and accuracy of bone localization.

Together, these studies support the safety, effectiveness, and robustness of BoneXpert under clinically representative conditions in relation to the predicate device.

Conclusion

BoneXpert and EFAI Bonesuite XR Bone Age Pro Assessment System (BAP-XR-100) have the same intended use and similar indications, technological characteristics, and principles of operation. The differences between the devices do not change the intended use or raise different questions of safety or effectiveness. Clinical and bench testing demonstrate that BoneXpert performs as intended and supports substantial equivalence to the predicate device.

Visiana's BoneXpert Device Substantial Equivalence Comparison Table

	BoneXpert	EFAI Bonesuite XR Bone Age Pro Assessment System (BAP-XR-100)
Regulation Number and Product Code	21 CFR 892.2050 QIH	21 CFR 892.2050 QIH
Intended Use/Indications for Use	BoneXpert is designed to view and quantify bone age from 2D Posterior Anterior (PA) hand radiographs using machine learning techniques to aid in the analysis of bone age assessment of patients between 2-21 years old for pediatric radiologists. The results should not be relied upon alone to make diagnostic decisions. The images shall be without any major bone deformity and without excessive image postprocessing (edge enhancement).	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.
User Population	Pediatric Radiologist	Pediatric Radiologist
Input Images	X-ray of left or right hand	X-ray of left hand
Algorithm	Machine-learning-based	Deep-learning-based[H
Primary Output	Annotated image with information on bone age estimation based on Greulich-Pyle (GP) method	JSON message with structured information on bone age estimation based on Greulich-Pyle (GP) method
Secondary/Supplementary Outputs	Carpal Bone Age Reference Curve Bone Age Standard Deviation	N/A
Image Quality Filtering	Self-validation to ensure image processed is appropriate	N/A
Primary Performance	A lower RMSE (0.55 years) than a single manual rater (0.76 years) when compared against a three-rater reference, with large deviations (≥ 1.5 years) occurring in only 1.7% of BoneXpert assessments versus 6.4% of single manual ratings. The model-based analysis estimated BoneXpert's true accuracy at 0.41 years compared to overall human rater variability of 0.65 years, with BoneXpert providing more consistent performance across age strata than individual manual raters.	In 600 cases, 88% of cases had a difference of less than 0.5 years between the device output and ground truth, with Deming regression results showing an intercept of -0.07 (95% CI: [-0.13, -0.01]) and a slope of 1.00 (95% CI: [0.99, 1.00]).