July 17, 2024

AZmed SAS
Christelle Baille
Head of QARA
6 rue Léonard de Vinci
Laval, France, 53000

Re: K240845
Trade/Device Name: Rayvolve
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QBS
Dated: June 18, 2024
Received: June 18, 2024

Dear Christelle Baille:

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,

for

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

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)*
K240845

Device Name
Rayvolve

Indications for Use *(Describe)*
Rayvolve is a computer-assisted detection and diagnosis (CAD) software device to assist radiologists and emergency physicians in detecting fractures during the review of radiographs of the musculoskeletal system. Rayvolve is indicated for adult and pediatric population (≥ 2 years).

Rayvolve is indicated for radiographs of the following industry-standard radiographic views and study types.

Study type (Anatomic Area of interest) / Radiographic Views* supported:
Ankle/ AP, Lateral, Oblique
Clavicle/ AP, AP Angulated View
Elbow/ AP, Lateral
Forearm/ AP, Lateral
Hip /AP, Frog-leg lateral
Humerus /AP, Lateral
Knee/ AP, Lateral
Pelvis /AP
Shoulder/ AP, Lateral, Axillary
Tibia/fibula/ AP, Lateral
Wrist/ PA, Lateral, Oblique
Hand / PA, Lateral, Oblique
Foot/ AP, Lateral, Oblique.

*Definitions of anatomic area of interest and radiographic views are consistent with the ACR-SPR-SSR Practice Parameter for the Performance of Radiography of the Extremities guideline.

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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RAYVOLVE
510K Summary

Content

1. Submitter

Submitted date: 2024-07-15

Submitter	AZmed SAS 6 rue Léonard de Vinci 53000 Laval, France Phone: +33 6 43 31 51 38
Contact personn	Christelle BAILLE Head of QARA 6 rue Léonard de Vinci 53000 Laval, France Phone: +33 6 43 31 51 38 Mail: christelle@azmed.co

2. Device identification

Name of the Device	Common or Usual Name	Regulatory section	Classification	Product Code	Panel
Rayvolve	Rayvolve	21 CFR 892.2090	Class II	QBS	90 (Radiology)

3. Predicate device

The legally marketed device for which AZmed is claiming equivalence is identified as follows:

Manufacturer	Product Name	510K Number
AZmed	Rayvolve	K220164

4. Device description

The medical device is called Rayvolve. It is a standalone software that uses deep learning techniques to detect and localize fractures on osteoarticular X-rays. Rayvolve is intended to be used as an aided-diagnosis device and does not operate autonomously.

Rayvolve has been developed to use the current edition of the DICOM image standard. DICOM is the international standard for transmitting, storing, retrieving, printing, processing, and displaying medical imaging.
Using the DICOM standard allows Rayvolve to interact with existing DICOM Node servers (eg.: PACS) and clinical-grade image viewers. The device is designed for running on-premise, cloud platform, connected to the radiology center local network, and can interact with the DICOM Node server.

When remotely connected to a medical center DICOM Node server, Rayvolve directly interacts with the DICOM files to output the prediction (potential presence or absence of fracture) the initial image appears first, followed by the image processed by Rayvolve.

Rayvolve does not intend to replace medical doctors. The instructions for use are strictly and systematically transmitted to each user and used to train them on Rayvolve's use.

5. Intended use/Indication for use

Rayvolve is a computer-assisted detection and diagnosis (CAD) software device to assist radiologists and emergency physicians in detecting fractures during the review of radiographs of the musculoskeletal system. Rayvolve is indicated for the adult and pediatric population (≥ 2 years).
Rayvolve is indicated for radiographs of the following industry-standard radiographic views and study types.

Study type (Anatomic Area of interest) / Radiographic Views* supported:

- Ankle / AP, Lateral, Oblique
- Clavicle / AP, AP Angulated View
- Elbow / AP, Lateral
- Forearm / AP, Lateral
- Hip / AP, Frog leg lateral
- Humerus / AP, Lateral
- Knee / AP, Lateral
- Pelvis / AP
- Shoulder / AP, Lateral, Axillary
- Tibia/fibula / AP, Lateral
- Wrist / PA, Lateral, Oblique
- Hand / PA, Lateral, Oblique
- Foot / AP, Lateral, Oblique.

* Definitions of anatomic area of interest and radiographic views are consistent with the ACR-SPR-SSR Practice Parameter for the Performance of Radiography of the Extremities guideline.

6. Substantial equivalence Discussion

The comparison chart below provides evidence to facilitate the substantial equivalence determination between Rayvolve to the predicate device (K220164) concerning the intended use, technological characteristics, and principle of operation vice and the cited predicate device.

Comparison to predicate device	Rayvolve - Predicate (K220164)	Rayvolve - Subject device 510(k) file	Comparison to the predicate
Device Name	Rayvolve	Rayvolve	Same
Manufacturer	AZmed SAS	AZmed SAS	Same
510 (k) #	K220164	K240845	N/A
Regulation Number	21 CFR 892.2090	21 CFR 892.2090	Same
Class	II	II	Same
Product Code	QBS	QBS	Same
Device Panel	Radiology	Radiology	Same
Level of Concern	Moderate	Moderate	Same
Intended use / Indications for use	Rayvolve is a computer-assisted detection and diagnosis (CAD) software device to assist radiologists and emergency physicians in detecting fractures during the review of radiographs of the musculoskeletal system.	Rayvolve is a computer-assisted detection and diagnosis (CAD) software device to assist radiologists and emergency physicians in detecting fractures during the review of radiographs of the musculoskeletal system.	Same
Intended user	Radiologists and emergency physicians	Radiologists and emergency physicians	Same
Intended patient population	Adult ≥ 22 years old	Adult and pediatric population	The subject device is indicated for

Comparison to predicate device	Rayvolve - Predicate (K220164)	Rayvolve - Subject device 510(k) file	Comparison to the predicate
			pediatric (≥ 2 years) as well as adult patients.
Image modality	X-Ray	X-Ray	Same
Anatomic Areas of Interest	Ankle Clavicle Elbow Forearm Hip Humerus Knee Pelvis Shoulder Tibia/fibula Wrist Hand Foot	Ankle Clavicle Elbow Forearm Hip Humerus Knee Pelvis Shoulder Tibia/fibula Wrist Hand Foot	Same
Clinical findings	Fractures	Fractures	Same
Machine learning technology	Supervised Deep learning	Supervised Deep learning	Same
Image source	DICOM node (e.g, imaging device, intermediate, DICOM node, PACS system, etc)	DICOM node (e.g, imaging device, intermediate, DICOM node, PACS system, etc)	Same
Image viewing	PACS system Image annotations toggled on or of	PACS system Image annotations toggled on or of	Same
Privacy	HIPAA Compliant	HIPAA Compliant	Same
Platform	On-premise, on cloud, secure local processing and delivery of DICOM images (eg:PACS)	On-premise, on cloud, secure local processing and delivery of DICOM images (eg:PACS)	Same
Electromagnetic compatibility and electrical safety	N/A, Rayvolve is a standalone software and is not subject to	N/A, Rayvolve is a standalone software and is not subject to	Same

Comparison to predicate device	Rayvolve - Predicate (K220164)	Rayvolve - Subject device 510(k) file	Comparison to the predicate
	electromagnetic testing. Therefore no electromagnetic compatibility and electrical safety is required.	electromagnetic testing. Therefore no electromagnetic compatibility and electrical safety is required.	
Magnetic resonance	N/A, Rayvolve is a standalone software and is not subject to magnetic resonance. Therefore no magnetic testing is required.	N/A, Rayvolve is a standalone software and is not subject to magnetic resonance. Therefore no magnetic testing is required.	Same
Animal and/or Cadever Testing	N/A, Rayvolve is a standalone software	N/A, Rayvolve is a standalone software	Same
Biocompatibility	N/A, Rayvolve is a standalone software with no direct or indirect patient or user contacting components. Therefore no biocompatibility is required.	N/A, Rayvolve is a standalone software with no direct or indirect patient or user contacting components. Therefore no biocompatibility is required.	Same

Table 2: Comparison between the predicate and subject devices

AZmed claims the substantial equivalence of Rayvolve with the predicate Rayvolve (K220164) based on the **functional principle** of the software algorithms, the same technological characteristics, and the **intended purpose** of the software algorithm.

7. Performance data

a. Software verification and validation testing

The device's software development, verification, and validation have been carried out by FDA guidelines. The software was tested against the established software design specification for each test plan to ensure the device's performance as intended. The device hazard analysis was completed and risk control was implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes. Rayvolve device passes all the testing and supports the claims of substantial equivalence with the predicate.

Validation activities included a usability study of Rayvolve under normal conditions for use. The study demonstrated:

- Non-invasive usability because users' habits are unchanged,
- Comprehension of the instructions for use provided with the device.

b. Bench Testing

i. Study on Pediatric population (≥ 2 years)

To include the pediatric population (≥ 2 years) in the indications for use of Rayvolve, AZmed conducted a standalone performance assessment on 3016 radiographs for all the study types (anatomic areas of interest) and views in the indication for Use. Within this standalone performance study, all the sensitivity, specificity, and AUC metrics have been computed per radiograph.

The results of standalone testing demonstrated that Rayvolve detects fractures of the musculoskeletal system radiographs with high sensitivity (0.9611, 95% Wilson's Confidence Interval (CI): 0.9480; 0.9710), high specificity (0.8597; 95% Wilson's CI: 0.8434; 0.8745) and high Area Under The Curve (AUC) of the Receiver Operating Characteristic (ROC) (0.9399; 95% Bootstrap CI: 0.9330; 0.9470).

Note: this study has been made on the following machines: Konica Minolta, IRay, AGFA, and GEHC.

The overall goal of the conducted study was to compare the diagnostic performances of Rayvolve on the pediatric (≥ 2 years) clinical performance study dataset to the diagnostic performances of Rayvolve on the adult clinical performance study dataset (included in the submission of the predicate device).

AZmed compares the AUC confidence intervals with those of the adult algorithm. Overlapping confidence intervals indicate that the pediatric software's performance is statistically non-inferior to the adult software, confirming similar efficacy in these regions.

The results of the study demonstrated that Rayvolve detects fractures in radiographs with high level performances :

	AUC (Bootstrapped CI)
All	0.9399 (0.9330; 0.9470)

Rayvolve performance on all radiographs

Anatomic Area	AUC (Bootstrapped CI)
Ankle	0.9489 (0.9257; 0.9694)
Clavicle	0.9263 (0.8846; 0.9645)
Elbow	0.9308 (0.8932; 0.9629)
Foreram	0.936 (0.9012; 0.9666)
Humerus	0.9568 (0.9268; 0.9818)
Hip	0.947 (0.922; 0.9681)
Knee	0.9624 (0.9472; 0.9756)
Pelvis	0.9263 (0.8947; 0.9559)
Shoulder	0.9372 (0.9037; 0.9664)
Tibia/Fibula	0.9616 (0.9362; 0.9824)
Wrist	0.9484 (0.9258; 0.9688)
Hand	0.9485 (0.9306; 0.9654)
Foot	0.9404 (0.9211; 0.9581)

Rayvolve performances regarding the anatomic area of the study

Ethnicity	AUC (Bootstrapped CI)
Caucasian	0.944 (0.9331; 0.9548)
Hispanic	0.948 (0.9362; 0.9589)
African-American	0.9542 (0.9335; 0.9724)
Asian	0.9272 (0.8932; 0.9588)
Others	0.9308 (0.9087; 0.9503)

Rayvolve performances regarding the ethnicity site

For pediatric anatomical regions, Rayvolve was not found to perform as well as the adults in the performance test dataset. However, the results demonstrated that Rayvolve performs with high accuracy across study types and potential confounders (anatomic areas of interest, views, patient age, and sex, image acquisition, types of fractures, weight-bearing and non-weight bearing bone fractures, and different X-ray system manufacturers).

ii. Study on the Adult population

1. Rayvolve predicate (K220164)

For Rayvolve predicate (K220164), AZmed conducted a standalone performance assessment on 2626 radiographs for all the study types (anatomic areas of interest) and views in the Indications for Use. The results of standalone testing demonstrated that Rayvolve detects fractures of the musculoskeletal system radiographs with high sensitivity (0.98763, 95% Wilson's Confidence Interval (CI): 0.97559; 0.99421), high specificity (0.88558; 95% Wilson's CI: 0.87119; 0.89882) and high Area Under The Curve (AUC) of the Receiver Operating Characteristic (ROC) (0.98607; 95% Bootstrap CI: 0.98104; 0.99058).
Additionally, the results demonstrated that Rayvolve performs with high accuracy across study types (anatomic areas of interest, views, patient age, sex, and machine) and across potential confounders such as different X-ray manufacturers.
Note: this study has been made on the following machines: Philips DigitalDiagnost, Carestream Health DRX-1, and GEHC.

The results of the standalone testing demonstrated that Rayvolve detects fractures of the musculoskeletal system radiographs with high AUC across the following subgroups:

	AUC (Bootstrapped CI)
All	0.98607 (0.98104; 0.99058)

Rayvolve performance on all radiographs

Anatomic Area	AUC (Bootstrapped CI)
Ankle	0.99137 (0.98374; 0.99727)
Clavicle	0.97806 (0.94626; 0.99761)
Elbow	0.9964 (0.99059; 1.0)
Forearm	0.9953 (0.98909; 0.99937)
Humerus	0.9955 (0.98960; 0.99943)
Hip	0.95821 (0.93239; 0.98014)
Knee	0.97742 (0.95084; 0.99592)
Pelvis	0.97676 (0.95241; 0.99638)
Shoulder	0.97814 (0.94147; 0.99958)
Tibia/Fibula	0.98285 (0.95925; 0.9978)
Wrist	0.99567 (0.99126; 0.99897)
Hand	0.99552 (0.99074; 0.99898)
Foot	0.99162 (0.98238; 0.99823)

Rayvolve performances regarding the anatomic area of the study

2. Rayvolve retrained algorithm

Performed study for the retrained algorithm

The core design of the Rayvolve algorithm, including the object detection model, remains unchanged from the predicate device (Rayvolve K220164). The architecture and key components are consistent with those previously described.

The training dataset for the subject device was expanded to include 150,000 osteoarticular radiographs, compared to 115,000 in the predicate device. This expansion was undertaken to enhance the algorithm's robustness by including a more comprehensive representation of pediatric cases alongside adult cases. The algorithm was retrained using the expanded dataset, which involved adjusting the model weights to optimize performance across the broader dataset that includes both adult and pediatric populations. The previous truthed predicate test dataset was strictly walled off and not included in the new training dataset.

Following the retraining, AZmed conducted a performance study using the same testing methodologies applied to the predicate device. The results of this study show that the retrained algorithm performs non-inferiority across all body parts compared to the predicate device.

Anatomic Area	AUC (Bootstrapped CI)	
	Predicate	Re-trained
Ankle	0.99137 (0.98374; 0.99727)	0.99732 (0.98969; 1)
Clavicle	0.97806 (0.94626; 0.99761)	0.98393 (0.95118; 0.99949)
Elbow	0.9964 (0.99059; 1.0)	0.99441 (0.98761; 0.99701)
Foreram	0.9953 (0.98909; 0.99937)	0.9943 (0.98809; 0.99737)
Humerus	0.9955 (0.98960; 0.99943)	0.99351 (0.98662; 0.99644)
Hip	0.95821 (0.93239; 0.98014)	0.95725 (0.93236; 0.97918)

Anatomic Area	AUC (Bootstrapped CI)	
	Predicate	Re-trained
Knee	0.97742 (0.95084; 0.99592)	0.9784 (0.95182; 0.9969)
Pelvis	0.97676 (0.95241; 0.99638)	0.97774 (0.95339; 0.99836)
Shoulder	0.97814 (0.94147; 0.99958)	0.98303 (0.94542; 1)
Tibia/Fibula	0.98285 (0.95925; 0.9978)	0.98776 (0.96512; 0.99872)
Wrist	0.99567 (0.99126; 0.99897)	0.99567 (0.99126; 0.99797)
Hand	0.99552 (0.99074; 0.99898)	0.99452 (0.98875; 0.99698)
Foot	0.99162 (0.98238; 0.99823)	0.99757 (0.98735; 1)
Total	0.98607 (0.98104; 0.99058)	0.98781 (0.98247; 0.99048)

Rayvolve performances regarding the retrained algorithm

Non-inferiority testing

AZmed acceptance criteria for non-inferiority adult testing involve a margin of 0.05. Using the bootstrap method to compare the AUCs (Area Under the Curve), this approach, which assumes minimal distributional assumptions, helps assess the variability and confidence intervals of the AUC values. If the lower bound of the difference in AUCs (Retrained - Predicate) exceeds -0.05, non-inferiority is confirmed.

Based on the calculated differences and their confidence intervals, we can conclude non-inferiority for all organs when using a non-inferiority margin of -0.05. The lower bounds of the differences in AUCs for the Retrained model compared to the Predicate model are all greater than -0.05, indicating that the Retrained model's performance is not inferior to the Predicate model across all organs.

c. Clinical data

No clinical studies were conducted in support of the 510(k) submission of Rayvolve.

Rayvolve is based on the same AI algorithm as the predicate device: Rayvolve (K220164).
AZmed conducted a fully crossed multiple readers, multiple case (MRMC) retrospective reader study to determine the impact of Rayvolve on reader performance in diagnosing fractures.

The primary objective of the study was to determine whether the diagnostic accuracy of readers aided by Rayvolve ("Rayvolve-aided") is superior to the diagnostic accuracy of readers unaided by Rayvolve ("Rayvolve-unaided") as determined by the AUC of the Receiver Operating Characteristic (ROC) Curve. The secondary objective is to report the sensitivity and specificity of the Rayvolve-aided and unaided reads.

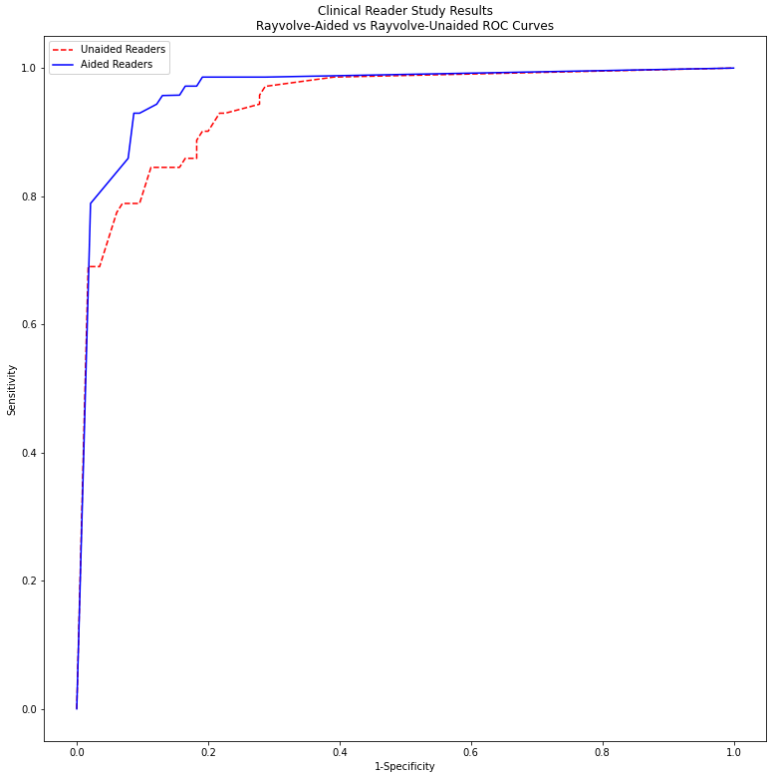
24 clinical readers each evaluated 186 cases in Rayvolve's indication for use under both Rayvolve-aided and Rayvolve-unaided conditions. Each case had been previously evaluated by a panel of three US board-certified MSK radiologists to provide ground truth binary labeling indicating the presence or absence of fracture and the localization information for fractures. The MRMC study consisted of two independent reading sessions separated by a washout period of at least one month to avoid memory bias.

For each case, each reader was required to provide a binary determination of the presence or absence of a fracture and also to draw a bounding box around each fracture on the image to determine the localization of each fracture.

In addition to this binary decision of the readers regarding the presence or absence of fracture, each reader should also provide a report score with an ordinal value.

This report score has been collected for every case and every reader with and without the aid of the Rayvolve device. The report score has been used for ROC data.
The results of the study found that the diagnostic accuracy of readers in the intended use population is superior when aided by Rayvolve than when unaided by Rayvolve, as measured at the task of fracture detection using the AUC of the ROC curve as calculated by the DBM modeling approach.

Clinical Reader Study Results
Rayvolve-Aided vs Rayvolve-Unaided ROC Curves



In particular, the study results demonstrated:

- Reader AUC was significantly improved from 0.84602 to 0.89327, a difference of 0.04725 (95% CI: 0.03376; 0.061542), across the 186 cases within Rayvolve's Indications for Use, spanning 13 study types (anatomic areas of interest) (p=0.0041).
- Reader sensitivity was significantly improved from 0.86561 (95% Wilson's CI: 0.84859, 0.88099) to 0.9554 (95% Wilson's CI: 0.94453, 0.96422)
- Reader specificity was improved from 0.82645 (95% Wilson's CI: 0.81187, 0.84012) to 0.83116 (95% Wilson's CI: 0.81673, 0.84467)

8. CONCLUSION

Both the proposed device (Rayvolve) and the predicate device are computer-assisted detection and diagnostic devices that accept as input radiographs in DICOM format and use machine learning techniques to identify and highlight fractures in the adult and pediatric population (≥2 years). The overall design and development of the software show that the device performs as intended and the differences in indications for use including the new patient population (pediatric ≥ 2 years) do not raise different questions of safety and effectiveness. The results of standalone and clinical studies demonstrate that Rayvolve performs according to the specifications and meets user needs and intended use.
Therefore, the Rayvolve subject device and the Rayvolve predicate device (K220164) are substantially equivalent.