



May 12, 2026

AZmed
Shanni Zeitoun
QARA Team
10 Rue D'Uzès
Paris,
France

Re: K260378

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: April 1, 2026
Received: April 1, 2026

Dear Shanni Zeitoun:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

 for

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.

K260378

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Please provide the device trade name(s).

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Rayvolve

Please provide your Indications for Use below.

?

Rayvolve is a computer-assisted detection and diagnosis (CAD) software device to assist radiologists and emergency physicians in detecting fractures, joint effusions and dislocations 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.

Rayvolve is indicated for use in adult and pediatric populations to help detect fracture, dislocations and joint effusions on osteoarticular X-rays of the following anatomic area of interest/radiographic views:

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

- 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.
- Ribs AP
- Spine PA, Lateral

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

- Shoulder / AP, Lateral, Axillary
- Elbow / AP, Lateral
- Hand / PA, Lateral, Oblique

Study type (Anatomic Area of interest) / Radiographic Views* supported for joint effusion detection:

- Elbow / AP, Lateral
- Forearm / AP, Lateral
- Arm / AP, Lateral

*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.

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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RAYVOLVE 510K Summary

1. Submitter

Submitted date: 2026-02-04

Submitter	AZmed SAS 6 rue Léonard de Vinci 53000 Laval, France Phone: +33 6 43 31 51 38
Contact person	Shanni ZEITOUN QARA team 6 rue Léonard de Vinci 53000 Laval, France Phone: +33 6 67 36 64 93 Mail: shanni@azmed.co

Table 1: Submitter information

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)

Table 2: Device identification

3. Predicate device

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

Manufacturer	Product Name	510K Number
AZmed	Rayvolve	K240845

Table 3: Predicate device

4. Device description

The medical device is called Rayvolve. It is a standalone software that uses machine learning techniques to detect and localize fractures, dislocations, and joint effusions on osteoarticular X-rays. Rayvolve is intended to be used as an aided diagnosis device and does not operate autonomously. It is intended to work in combination with DICOM node servers. 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, dislocation, or joint effusion).

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 Picture Archive and Communication Systems (e.g., PACS), and clinical-grade image viewers. The device is designed for running on a cloud platform and connected to the radiology center's local network, and can interact with the DICOM Node server.

Rayvolve filters and downloads only X-rays with modalities (CR and DX) and organs determined from the DICOM Node server.

Abnormalities are directly identified on the X-ray by bounding zones, and if there is no abnormality, a sentence at the top of the X-ray indicates it. After analysis, the device sends edited X-rays to the DICOM Node server.

Note: The initial image in the DICOM Node server is by no means deleted or modified.

When the radiologist downloads the images to be analyzed from the DICOM Node server to his workstation (DICOM Node server-client), the initial image appears first, followed by the image processed by Rayvolve.

The analyzed images help radiologists and physicians to diagnose abnormalities.

Note: 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 and indication for use

Rayvolve is a computer-assisted detection and diagnosis (CAD) software device to assist radiologists and emergency physicians in detecting fractures, joint effusions and dislocations 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.

Rayvolve is indicated for use in adult and pediatric populations to help detect fracture, dislocations and joint effusions on osteoarticular X-rays of the following anatomic area of interest/radiographic views:

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

- 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.
- Ribs AP
- Spine PA, Lateral

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

- Shoulder / AP, Lateral, Axillary
- Elbow / AP, Lateral
- Hand / PA, Lateral, Oblique

Study type (Anatomic Area of interest) / Radiographic Views* supported for **joint effusion** detection:

- Elbow / AP, Lateral
- Forearm / AP, Lateral
- Arm / AP, Lateral

** 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 (K240845) concerning the intended use, technological characteristics, and principle of operation versus the cited predicate device.

Comparison to predicate device	Rayvolve - Predicate (K240845)	Rayvolve - Subject device 510(k) file (K260378)	Comparison to the predicate
Device Name	Rayvolve	Rayvolve	Same
Manufacturer	AZmed SAS	AZmed SAS	Same
510 (k) #	K240845	K260378	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

Comparison to predicate device	Rayvolve - Predicate (K240845)	Rayvolve - Subject device 510(k) file (K260378)	Comparison to the predicate
Intended 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 and pediatric population	Adult and pediatric population	Same
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 Spine Ribs	Expanded anatomy; does not alter intended use
Clinical findings	Fractures	Fractures, dislocations and joint effusions	Expanded pathology scope; addressed via clinical data.
Machine learning technology	Supervised Deep learning	Supervised Deep learning	Same
Image source	DICOM node (e.g, imaging device,	DICOM node (e.g, imaging device, intermediate,	Same

Comparison to predicate device	Rayvolve - Predicate (K240845)	Rayvolve - Subject device 510(k) file (K260378)	Comparison to the predicate
	intermediate, DICOM node, PACS system, etc)	DICOM node, PACS system, etc)	
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
Warnings	Rayvolve is an adjunct tool and does not replace the role of the users: they must not use the output of Rayvolve as primary interpretation. The users may use Rayvolve only for the intended anatomical regions indicated in this operating manual. The users may rely on their own diagnostic if ever Rayvolve detects fractures from anatomical areas outside the indication for use. The same bounding box can contain several adjacent fractures: the users shall proceed to a concurrent read with the original X-ray. It is possible that a bounding box hides a part of an adjacent fracture; the users shall proceed to a concurrent read with the original X-ray.	The images provided by Rayvolve are AI-aided automated analysis only. It shall not replace a physician's diagnosis. A disclaimer is displayed on the duplicate and the report generated by Rayvolve. The users may use Rayvolve only for the intended anatomical regions indicated in this operating manual. Rayvolve is not intended to detect abnormalities from anatomical areas of interest outside the indication for use, the users should review original images for all other suspected pathologies and other anatomical regions and shall rely on their own diagnostic if ever Rayvolve detects abnormalities from anatomical areas outside the indication for use. The same bounding zone	Same, only wording improvement.

Comparison to predicate device	Rayvolve - Predicate (K240845)	Rayvolve - Subject device 510(k) file (K260378)	Comparison to the predicate
	Rayvolve is not intended to detect fractures in other modalities than X-rays Rayvolve is not intended to detect fractures from anatomical areas of interest outside the indication for use: user should review original images for all other suspected pathologies and other anatomical regions Poor image quality can affect Rayvolve's detection of fracture: the users shall proceed to a concurrent read with the original X-ray. In the event of a significant change in Rayvolve's performance, please contact AZmed. Rayvolve is a diagnostic aid, only the users' diagnosis remain valid for the patient. Any serious incident occurring in connection with the device should be notified to AZmed and to the FDA.	can contain several adjacent pathologies: the users shall proceed to a concurrent read with the original X-ray. It is possible that a bounding zone hides a part of an adjacent pathology. The users shall proceed to a concurrent read with the original X-ray Rayvolve is not intended to detect pathologies in other modalities than X-rays. Poor image quality can affect Rayvolve's detection of pathologies: the users shall proceed to a concurrent read with the original X-ray In the event of a significant change in Rayvolve's performance, please contact AZmed. Rayvolve is a diagnostic aid, only the users' diagnosis remains valid for the patient. Any serious incident occurring in connection with the device should be notified to AZmed and to the competent authority.	
Electromagnetic compatibility and electrical safety	N/A, Rayvolve is a standalone software and is not subject to electromagnetic testing. Therefore no electromagnetic	N/A, Rayvolve is a standalone software and is not subject to electromagnetic testing. Therefore no electromagnetic	Same

Comparison to predicate device	Rayvolve - Predicate (K240845)	Rayvolve - Subject device 510(k) file (K260378)	Comparison to the predicate
	compatibility and electrical safety is required.	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 Cadaver 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
Output	Abnormality localization (fracture)	Abnormality localization (fracture, dislocation (shoulder, elbow, hand), and effusion (elbow/forearm/arm))	Same Output structure.
Risk Profile	Risk of FN/FP on MSK fractures	Risk of FN/FP on MSK abnormalities (same risk types)	Same risk nature

Table 4: Comparison between the predicate and subject devices

AZmed claims the substantial equivalence of Rayvolve with the predicate Rayvolve (K240845) based on the same **functional principle** of the software algorithms, the same technological characteristics, and the **intended purpose** of the software algorithm. Any differences between the devices do not raise new questions of safety or effectiveness.

7. Performance data

a. Software verification and validation testing

Software development, verification, and validation activities for the device were conducted in accordance with applicable FDA guidance. The software was verified



and validated against the defined software requirements to confirm that the device performs as intended.

A device hazard analysis was performed, and appropriate risk control measures were implemented to mitigate identified risks. The results of software testing demonstrate that all software requirements were met and that the device functions as intended. These results support the substantial equivalence of the Rayvolve device to the predicate device.

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. Standalone performance study

To include spine and ribs fractures, and dislocations and joint effusions, AZmed conducted a standalone performance assessment on 6246 radiographs to detect:

- Fractures (cervical spine, thoracic spine, lumbar spine, ribs)
- Dislocations (shoulder, elbow, hand (finger))
- Effusions (elbow, forearm, arm)

for all 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 MSK abnormalities on MSK X-rays with high sensitivity (96.88%, 95% Wilson's Confidence Interval (CI): 96.10%; 97.51), high specificity (87.29%; 95% Wilson's CI: 86.21%; 88.30%) and high Area Under The Curve (AUC) of the Receiver Operating Characteristic (ROC) (97.47%; 95% Bootstrap CI: 97.05%; 97.88%) at the case-level.

ANATOMICAL AREA	AUC (Bootstrapped CI)	Sensitivity (95% Wilson's CI)	Specificity (95% Wilson's CI)
C-Spine	0.9581 (0.9406; 0.9736)	TP=218 FP=51 TN=304 FN=8	
		0.9646 (0.9317; 0.9820)	0.8563 (0.8160; 0.8890)
T-Spine	0.9604 (0.9442; 0.9743)	TP=270 FP=62 TN=398 FN=11	
		0.9609 (0.9313; 0.9780)	0.8652 (0.8310; 0.8934)
L-Spine	0.9662 (0.9527; 0.9774)	TP=223 FP=62 TN=354 FN=8	
		0.9654	0.8510

		(0.9332; 0.9823)	(0.8135; 0.8820)
Rib	0.9743 (0.9640; 0.9841)	TP=316 FP=56 TN=452 FN=7	
		0.9783 (0.9559; 0.9895)	0.8898 (0.8595; 0.9141)
Shoulder Dislocation	0.9687 (0.9520; 0.9828)	TP=222 FP=54 TN=327 FN=7	
		0.9694 (0.9383; 0.9851)	0.8583 (0.8197; 0.8897)
Elbow Dislocation	0.9720 (0.9565; 0.9862)	TP=189 FP=46 TN=271 FN=7	
		0.9643 (0.9281; 0.9826)	0.8549 (0.8119; 0.8894)
Hand Dislocation (Finger)	0.9798 (0.9657; 0.9909)	TP=173 FP=37 TN=269 FN=5	
		0.9719 (0.9359; 0.9879)	0.8791 (0.8378; 0.9110)
Elbow Joint Effusion	0.9785 (0.9674; 0.9885)	TP=277 FP=59 TN=467 FN=7	
		0.9754 (0.9500; 0.9880)	0.8878 (0.8580; 0.9120)
Forearm Joint Effusion	0.9652 (0.9457; 0.9817)	TP=163 FP=26 TN=207 FN=6	
		0.9645 (0.9247; 0.9836)	0.8884 (0.8415; 0.9227)
Arm Joint Effusion	0.9666 (0.9514; 0.9798)	TP=219 FP=43 TN=358 FN=7	
		0.9690 (0.9375; 0.9849)	0.8928 (0.8587; 0.9194)

Table 5 - Rayvolve performance per anatomic areas on all radiographs.

The results of the study demonstrated that Rayvolve:

- detects fractures, dislocations and effusions in radiographs with similar performances on the adult population and on the pediatric population (≥ 2 years),
- performs with high accuracy across study types (anatomic areas of interest, views, patient age, patient position, sex and machine) and across potential confounders such as different X-ray manufacturers.

ii. MRMCM

AZmed conducted two multi-reader, multi-case (MRMC) retrospective studies to determine the impact of Rayvolve on reader performance in diagnosing dislocations. A first MRMC study investigated 178 MSK radiographs across various confounders. A second MRMC was carried out on 225 MSK radiographs to evaluate the impact of Rayvolve on readers' performance per view of acquisition. Twenty readers, including ten specialists (MSK radiologists) and ten non-specialists

(from other specialties), identified dislocations without AI and then with AI assistance in two sessions, separated by a one-month washout period.

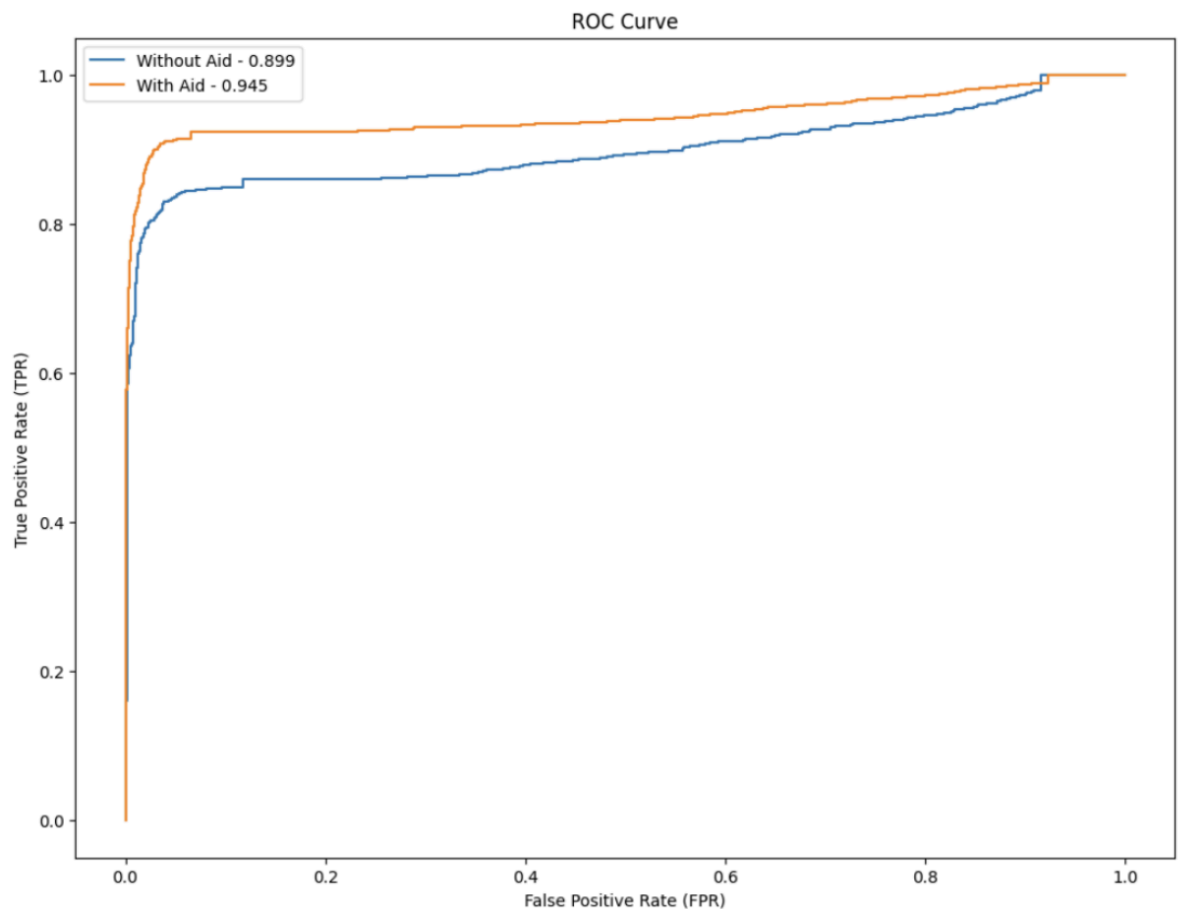
Within this MRMC study, all the sensitivity, specificity, and AUC metrics have been computed per image.

The study demonstrated an improvement in the performance of readers per image when aided by Rayvolve as measured by the AUC. The AUC in Rayvolve aided reads (0.9451 (95% CI: 0.9380; 0.9523)) is higher than in Rayvolve unaided reads (0.8989 (95% CI: 0.8892; 0.9087)).

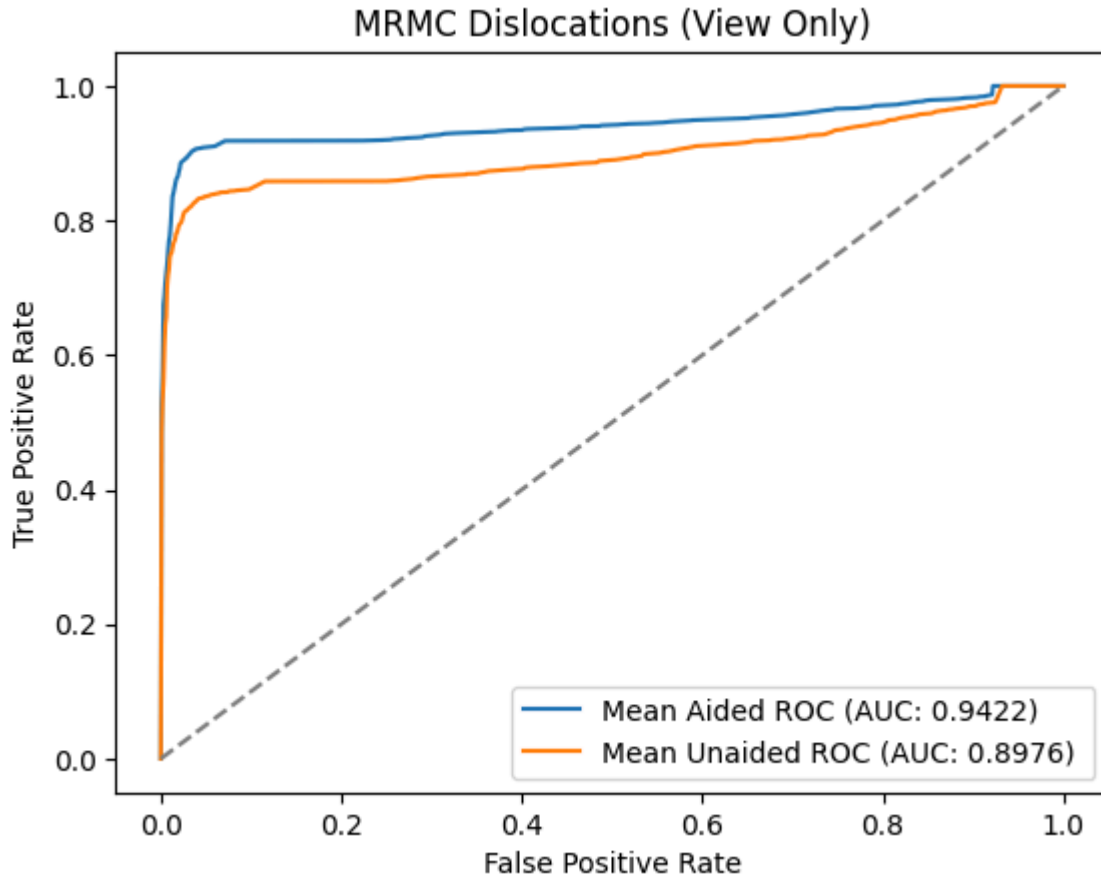
In particular, at an image level, the results demonstrated that:

- Reader sensitivity per image was significantly improved from 0.8489 (95% Wilson's CI: 0.8315; 0.8648) to 0.9146 (95% Wilson's CI: 0.9007; 0.9267)
- Reader specificity per image was improved from 0.8826 (95% Wilson's CI: 0.8668; 0.8967) to 0.9343 (95% Wilson's CI: 0.9218; 0.9449)
- Reader analysis time per image was improved from 27.25 seconds to 23.42 seconds, a difference of 3.8 seconds, thus the analysis time has been reduced by 14%.

❖ First MRMC



❖ Second MRMC



Area Under the Curve (AUC) of the Receiver Operating Characteristic curve (ROC) of the second MRMC (image-level).

iii. Clinical data

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

8. Conclusion

Both the proposed device (Rayvolve) and the predicate device (K240845) are computer-assisted detection and diagnostic devices that accept as input radiographs in DICOM format and use machine learning techniques to identify and highlight pathologies 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 addition of spine, and ribs fractures, dislocations and joint effusion detection do not raise different questions of safety and effectiveness.

The results of standalone and the MRMCs 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 (K240845) are substantially equivalent.