August 28, 2026

AZmed
% Victor DE POLLI
QARA Associate
10 Rue D'Uzès
PARIS, 75002
FRANCE

Re: K261378
Trade/Device Name: Rayvolve AZchest
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QBS
Dated: July 29, 2026
Received: July 29, 2026

Dear Victor DE POLLI:

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,

for 

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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.	K261378

Please provide the device trade name(s).

Rayvolve AZchest

Please provide your Indications for Use below.

Rayvolve AZchest is a radiological computer-assisted detection and diagnosis (CADe/x) software device that analyzes frontal chest radiographs for the presence of specific targeted pathologies within the Pleura, Mediastinum, and Parenchyma.

Rayvolve uses deep learning techniques to detect, identify, and provide diagnostic outputs by labeling Regions of Interest (ROIs). The device highlights ROIs using bounding boxes for Pleural effusion, Consolidation and increased cardiothoracic ratio (CTR). For Pneumothorax, the device highlights ROIs using bounding boxes or contours to assist in the diagnosis of this condition.

Detection of Pleural effusion, Pneumothorax, and increased CTR is indicated only for chest radiographs acquired in the erect or semi-erect positions. Detection of Consolidation is indicated for chest radiographs acquired in erect, semi-erect, or supine positions.
Rayvolve AZchest is not indicated for the analysis of non-diagnostic images (e.g., due to severe motion artifacts or exposure issues).

Rayvolve AZchest is intended for use as a second-reading aid for radiologists. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.
It does not replace the role of radiologists or of other diagnostic testing in the standard of care.

Rayvolve AZchest is for prescription use only and is indicated for adult and pediatric patients (aged 18 years and older) only.

Please select the types of uses.	☒ 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)

azmed

Rayvolve AZchest

510(k) Summary

K261378

azmed

1. Submitter

Submitted date: 2026-04-27

Submitter	AZmed 6 rue Léonard de Vinci 53000 Laval, FRANCE Phone: +33 6 72 19 04 19
Contact person	Victor DE POLLI QARA Associate 10, rue d'Uzès 75002 Paris, FRANCE Phone: +33 6 44 94 38 00 Mail: victor@azmed.co

Table 1: Submitter information

2. Device identification

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

Table 2: Device identification

3. Predicate device and reference device

Primary Predicate Device
Device Name: Rayvolve
Manufacturer: AZmed
510(k) Number: K260378
Regulation Number: 21 CFR 892.2090
Product Code: QBS

Reference Device
Device Name: Critical Care Suite
Manufacturer: GE Healthcare
510(k) Number: K223491
Regulation Number: 21 CFR 892.2090
Product Code: QBS

While K260378 serves as the primary predicate to establish the identical intended use (CADe/x second reading aid) and core technological characteristics, K223491 is included strictly as a Reference Device. In accordance with FDA guidance, the reference device is utilized to support Decision Point 5a by demonstrating a well-established technological characteristic among legally marketed devices: the provision of CADe/x localization outputs on frontal chest radiographs as an aid to the interpreting physician. This confirms that the application of this technology to chest X-rays is a standard and safely mitigated clinical methodology.

4. Device description

Rayvolve AZchest is a radiological computer-assisted detection and diagnosis (CADe/x) software device that analyzes frontal chest radiographs for the presence of specific targeted pathologies within the Pleura, Mediastinum, and Parenchyma.

Rayvolve uses deep learning techniques to detect, identify, and provide diagnostic outputs by labeling Regions of Interest (ROIs). The device highlights ROIs using bounding boxes for Pleural effusion, Consolidation and increased cardiothoracic ratio (CTR). For Pneumothorax, the device highlights ROIs using bounding boxes or contours to assist in the diagnosis of this condition.

Detection of Pleural effusion, Pneumothorax, and increased CTR is indicated only for chest radiographs acquired in the erect or semi-erect positions. Detection of Consolidation is indicated for chest radiographs acquired in erect, semi-erect, or supine positions.

Rayvolve AZchest is not indicated for the analysis of non-diagnostic images (e.g., due to severe motion artifacts or exposure issues)

Rayvolve AZchest is intended for use as a second-reading aid for radiologists. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It does not replace the role of radiologists or of other diagnostic testing in the standard of care.

Rayvolve AZchest is for prescription use only and is indicated for adult and pediatric patients (aged 18 years and older) only.

Rayvolve AZchest is intended to work in combination with DICOM node servers. When remotely connected to a medical center DICOM Node server, Rayvolve AZchest directly interacts with the DICOM files to output the prediction (potential presence or absence of Pleural effusion, Consolidation, increased cardiothoracic ratio and Pneumothorax).

Rayvolve AZchest 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 AZchest 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.

Abnormalities are directly identified and labeled on the X-ray using bounding boxes. For Pneumothorax identification, a contouring visualization is also available.

Technologically, these contours are derived directly from the model’s internal feature maps, rather than simply drawing a standard rectangular bounding box. The generated contour is strictly a spatial subset of the predicted bounding box. By anchoring the contour to the core object detection feature maps, we ensure that the device's performance metrics (Sensitivity and Specificity) remain intrinsically tied to the validated detection algorithm. The rendering of the contour does not alter the underlying 'Positive' or 'Negative' output of the model; therefore, it introduces no new fundamental scientific technology.

Clinically, this contouring feature is a UI/UX enhancement designed specifically to minimize the 'occlusion effect' common in standard bounding boxes. Because a pneumothorax typically presents as a thin, curvilinear finding along the pleural space, a rectangular box would inevitably enclose a large area of healthy lung tissue, causing unnecessary visual clutter. Importantly, the device does not claim to perform clinical 'Segmentation'. The contour represents an algorithmic confidence distribution intended to guide the user's eye, rather than an exact anatomical measurement of the visceral pleura.

To mitigate any risk of over-reliance, the device labeling and operating manual explicitly state that the contour is a localization aid only. Users are instructed that the pathology may extend beyond the visualized contour and that the original, unannotated pixels must always be inspected.

Finally, this graphical UI is supplemented by textual information. At the top of the X-ray, a header explicitly lists the specific ROIs that were detected. At the bottom, a footer provides a clear negative predictive statement (e.g., *"No ROIs detected"*), followed by a list of all clinical findings within the Rayvolve AZchest indications for use that were analyzed but not identified. This dual approach ensures the clinician is fully informed of both the positive findings and the complete analytical scope of the device

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 physician 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 AZchest.

The analyzed images help physicians in their diagnosis.

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

5. Intended use and indication for use

5.1 Intended use

Rayvolve AZchest is a radiological computer-assisted detection and diagnosis (CADe/x) software device that analyzes frontal chest radiographs for the presence of specific targeted pathologies within the Pleura, Mediastinum, and Parenchyma.

5.2 Indication for use

Rayvolve AZchest is a radiological computer-assisted detection and diagnosis (CADe/x) software device that analyzes frontal chest radiographs for the presence of specific targeted pathologies within the Pleura, Mediastinum, and Parenchyma.

Rayvolve uses deep learning techniques to detect, identify, and provide diagnostic outputs by labeling Regions of Interest (ROIs). The device highlights ROIs using bounding boxes for Pleural effusion, Consolidation and increased cardiothoracic ratio (CTR). For Pneumothorax, the device highlights ROIs using bounding boxes or contours to assist in the diagnosis of this

condition.

Detection of Pleural effusion, Pneumothorax, and increased CTR is indicated only for chest radiographs acquired in the erect or semi-erect positions. Detection of Consolidation is indicated for chest radiographs acquired in erect, semi-erect, or supine positions.

Rayvolve AZchest is not indicated for the analysis of non-diagnostic images (e.g., due to severe motion artifacts or exposure issues).

Rayvolve AZchest is intended for use as a second-reading aid for radiologists. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It does not replace the role of radiologists or of other diagnostic testing in the standard of care.

Rayvolve AZchest is for prescription use only and is indicated for adult and pediatric patients (aged 18 years and older) only.

6. Substantial Equivalence Discussion

The comparison chart below provides evidence to facilitate the substantial equivalence determination between Rayvolve AZchest to the predicate device Rayvolve (K260378) concerning the intended use, technological characteristics, and principle of operation versus the cited predicate device.

Components and characteristics	**Subject device** AZmed Rayvolve AZchest	**Predicate device** AZmed Rayvolve - Predicate (K260378)
Regulation information		
Classification regulation	21 CFR 892.2090 – Radiological computer-assisted detection and diagnosis software.	Same
Product code	QBS	Same
Regulation description	A radiological computer-assisted detection and diagnostic software is an image processing device intended to aid in the detection, localization, and characterization of fracture, lesions, or other disease-specific findings on acquired medical images (e.g., radiography, magnetic resonance, computed tomography). The device detects, identifies, and characterizes findings based on features or information extracted from images, and provides information about the presence, location, and characteristics of the findings to the user. The analysis is intended to inform	Same

	the primary diagnostic and patient management decisions that are made by the clinical user. The device is not intended as a replacement for a complete clinician's review or their clinical judgment that takes into account other relevant information from the image or patient history.	
Indications for use		
Image Modality	X-ray	Same
Study type	Chest radiographs	MSK radiographs
Clinical Output	Identification of abnormalities in the regions of interest (ROIs) of Pleura, Mediastinum and Parenchyma on chest X-rays, and if there is no ROI, a sentence at the top of the X-ray indicates it. After analysis, the device sends edited X-rays to the DICOM Node server. Abnormalities identified are pneumothorax, consolidation, pleural effusion and increased cardiothoracic ratio (CTR). For Pneumothorax, the device identify ROIs using bounding boxes or contours.	Identification of abnormalities 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. Abnormalities identified are fractures, joint effusions and dislocations.
Intended users	Radiologists	Radiologists and emergency physicians
Intended user workflow	Device intended for use as a second-reading aid for users interpreting chest radiographs	Device intended for use as a concurrent reading aid for users interpreting musculoskeletal radiographs
Patient population	Adult and pediatric patients (aged 18 years and older) only	Adult and pediatric population
Technological information		
Machine learning technology	Supervised deep learning	Same
Deployment platform	On-premise or on cloud, secure processing and delivery of chest radiographs	Same
Image source	Digital X-ray	Same

Image viewing	Image displayed on PACS system	Same
Privacy	HIPAA compliant	Same
Electromagnetic compatibility and electrical safety	N/A, Rayvolve AZchest is a standalone software and is not subject to electromagnetic testing. Therefore no electromagnetic compatibility and electrical safety is required.	Same
Magnetic resonance	N/A, Rayvolve AZchest 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 AZchest is a standalone software	Same
Biocompatibility	N/A, Rayvolve AZchest is a standalone software with no direct or indirect patient or user contacting components. Therefore no biocompatibility is required.	Same

Table 4: Comparison between the predicate and subject devices

As outlined in the comparison table, Rayvolve AZchest shares the exact same intended use (radiological CADe/x) and fundamental scientific technology as the predicate device, Rayvolve (K260378).
In fact, Rayvolve AZchest and the predicate device represent two clinical verticals of the exact same core software product. Both utilize the identical supervised deep learning architecture, DICOM integration workflow, and deployment platforms (on-premise or cloud). Neither device is intended to replace the physician's review or clinical judgment.
Rayvolve AZchest differs from the predicate device strictly in its specific clinical application, encompassing three main aspects:

- **Anatomic Area and Targeted Findings:** Rayvolve AZchest is trained to analyze chest radiographs for specific thoracic pathologies (Pneumothorax, Pleural effusion, Consolidation and increased cardiothoracic ratio). In contrast, the predicate device analyzes musculoskeletal radiographs for fractures, dislocations, and joint effusions.
- **Patient Population:** Rayvolve AZchest is indicated strictly for adult and pediatric patients (aged 18 years and older) only, whereas the predicate includes pediatric patients.
- **Visualization Method:** While both verticals rely primarily on bounding boxes to localize abnormalities, Rayvolve AZchest introduces a contouring visualization option specifically for Pneumothorax to minimize visual occlusion on curvilinear pleural findings.

Although Rayvolve AZchest targets thoracic rather than musculoskeletal pathologies, it shares the exact same Intended Use (regulated under 21 CFR 892.2090 for CADe/x software) and core technological characteristics as the primary predicate (K260378). The fundamental mechanism of action, assisting the interpreting physician by detecting and localizing targeted pathologies via graphical overlays, remains identical. Consequently, this shift in anatomical

scope does not constitute a new intended use and does not raise new questions of safety or effectiveness.

To further support this specific clinical application, K223491 is cited as a Reference Device. It demonstrates that providing CADe/x localization outputs on frontal chest radiographs is a well-established technological characteristic among legally marketed devices, fully validating the safe application of our core technology to this anatomical region.

The safety and effectiveness of the device concerning these new specific chest pathologies, as well as the UI enhancement of the contouring visualization, are fully addressed and validated through the standalone and clinical performance data (MRMC) provided in the subsequent sections of this submission. Therefore, Rayvolve AZchest does not raise any new or different questions of safety and effectiveness and is considered substantially equivalent to the predicate device, Rayvolve (K260378).

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 AZchest device to the predicate device.

Validation activities included a usability study of Rayvolve AZchest 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

AZmed conducted a standalone assessment. In total, 8453 per-finding evaluations were performed and used for the standalone assessment (48% positives) for Rayvolve AZchest with respectively:

- 1999 images for pneumothorax, of which 941 positive radiographs and 1058 negative radiographs
- 1981 images for consolidation, of which 998 positive radiographs and 993 negative radiographs.
- 2040 images for pleural effusion, of which 979 positive radiographs and 1058 negative radiographs.
- 2433 images for increased cardiothoracic ratio, of which 1147 positive radiographs and 1286 negative radiographs.

	AUC	Per-image Sensitivity	Per-image Specificity	Per-mark Sensitivity
Pleural Effusion	0.9397 (0.9287; 0.9501)	0.9081 (0.8883; 0.9246)	0.9208 (0.9030; 0.9356)	0,8952 (0,8786; 0,9097)
Pneumothorax	0.9660 (0.9575; 0.9738)	0.9543 (0.9390; 0.9659)	0.8960 (0.8762; 0.9130)	0,9409 (0,9248; 0,9537)
Consolidation	0.9638 (0.9562; 0.9715)	0.9504 (0.9350; 0.9623)	0.8953 (0.8747; 0.9128)	0,9169 (0,902; 0,9297)
Increased CTR	0.9757 (0.9702; 0.981)	0.9695 (0.9579; 0.978)	0.8787 (0.8597; 0.8954)	0.9695 (0.9476; 0.9821)

Table 5 - Rayvolve AZChest performance per claimed pathologies

1. The AUC of the ROC curve was estimated for each abnormality, and remained high across all four, the highest being for increased cardiothoracic ratio (0.9757) and the lowest for pleural effusion (0.9411).
2. Sensitivity was calculated as well. Highest sensitivity was for increased cardiothoracic ratio (0.9695) and the lowest sensitivity for pleural effusion (0.9100).
3. In addition, Specificity was calculated. Highest was for pleural effusion (0.9217) and lowest for increased cardiothoracic ratio (0.8787).

Based on the comparative analysis of the standalone performance data, Rayvolve AZchest achieves a level of diagnostic accuracy that is highly comparable to the predicate device, Rayvolve (K260378).

- **Area Under the Curve (AUC):** The predicate device demonstrated high standalone AUCs ranging from 0.9581 to 0.9798 across MSK abnormalities. Similarly, the subject device, Rayvolve AZchest, maintained robust AUCs ranging from 0.9397 to 0.9757 across chest pathologies.

- **Sensitivity:** The predicate device exhibited sensitivities ranging from 0.9609 to 0.9783. The subject device achieved highly comparable sensitivities, ranging from 0.9081(for Pleural Effusion) to 0.9695 (for increased cardiothoracic ratio), proving its capability in detecting targeted thoracic abnormalities.

- **Specificity:** The predicate device showed specificities ranging from 0.8510 to 0.8928. The subject device demonstrated slightly higher specificities, ranging from 0.8787 to 0.9208, ensuring a low false-positive rate when analyzing chest radiographs.

Conclusion on Equivalence:
Both devices rely on the same fundamental deep learning architecture and exhibit robust, high-level performance metrics within their respective anatomical domains.
Despite the transition from musculoskeletal to thoracic imaging, the standalone performance of Rayvolve AZchest remains within the same high-accuracy ranges as the cleared predicate. This demonstrates that the change in targeted pathologies does not adversely affect the fundamental effectiveness of the algorithm.
Therefore, the standalone performance data strongly supports the substantial equivalence of Rayvolve AZchest to the predicate device Rayvolve.

ii. MRMC

AZmed conducted a Multiple Reader Multiple Case studies in order to demonstrate that Rayvolve AZchest improves the clinicians' performance in detecting and localizing chest abnormalities on chest radiographs.

The primary objective of the MRMC study was to determine whether the diagnostic accuracy of readers aided by Rayvolve AZchest is superior to reader accuracy when unaided by Rayvolve AZchest, as determined by the AUC of the ROC curve.

The secondary objective was to report the sensitivity and specificity per image of Rayvolve AZchest-aided and unaided reads, across different subgroup variables (age, sex, ethnicity, machine of acquisition, radiograph views, institution, position of acquisition and speciality).

Time was evaluated per-user performance and per-specialty performance at the image level.

The MRMC study comprised 1,489 per-finding case evaluations and was conducted from February 1 to April 18, 2024.

In total, the MRMC performance assessment was performed on:

- Pleural effusion on 349 radiographs, of which 166 positive radiographs and 183 negative radiographs.
- Pneumothorax on 259 radiographs, of which 121 positive radiographs and 138 negative radiographs.
- Consolidation on 400 radiographs, of which 200 positive radiographs and 200 negative radiographs.
- Increased cardiothoracic ratio on 277 radiographs, of which 139 positive radiographs and 138 negative radiograph

The cases were randomly sampled from the validation dataset used for the standalone assessment.

Twenty readers, including ten specialists (thoracic radiologists) and ten non-specialists (from other specialties), identified Pleural effusion, Consolidation, increased cardiothoracic ratio and Pneumothorax without AI and then with AI assistance in two sessions, separated by a one-month washout period.

For each case, each reader was asked to draw, if one of the following abnormality is present on the radiograph displayed on the viewer, the smallest rectangular area possible around it for pneumothorax, pleural effusion, consolidation and increased cardiothoracic ratio. The results of the MRMC testing demonstrated that Rayvolve AZchest improves the diagnostic accuracy of the readers, as determined by the increase of AUC of the ROC curve (aided vs unaided) for Pleural Effusion, Pneumothorax, Consolidation and increased cardiothoracic ratio. In addition, an increase of reader's sensitivity and specificity was demonstrated for all four.

	AUC Improvement (95% CI)	Sensitivity improvement (95% CI)	Specificity improvement (95% CI)
Pleural Effusion	0.0331 (0.0340; 0.0325)	0.0431 (0.0445; 0.0415)	0.0232 (0.0238; 0.0226)
Pneumothorax	0.0400 (0.0414; 0.0384)	0.0550 (0.0572; 0.0526)	0.0199 (0.0207; 0.0191)
Consolidation	0.0480 (0.0497; 0.0459)	0.0695 (0.0720; 0.0668)	0.0098 (0.0100; 0.0095)
Increased CTR	0.0318 (0.0427; 0.0209)	0.0446 (0.0629; 0.0263)	0.0406 (0.0572; 0.0240)

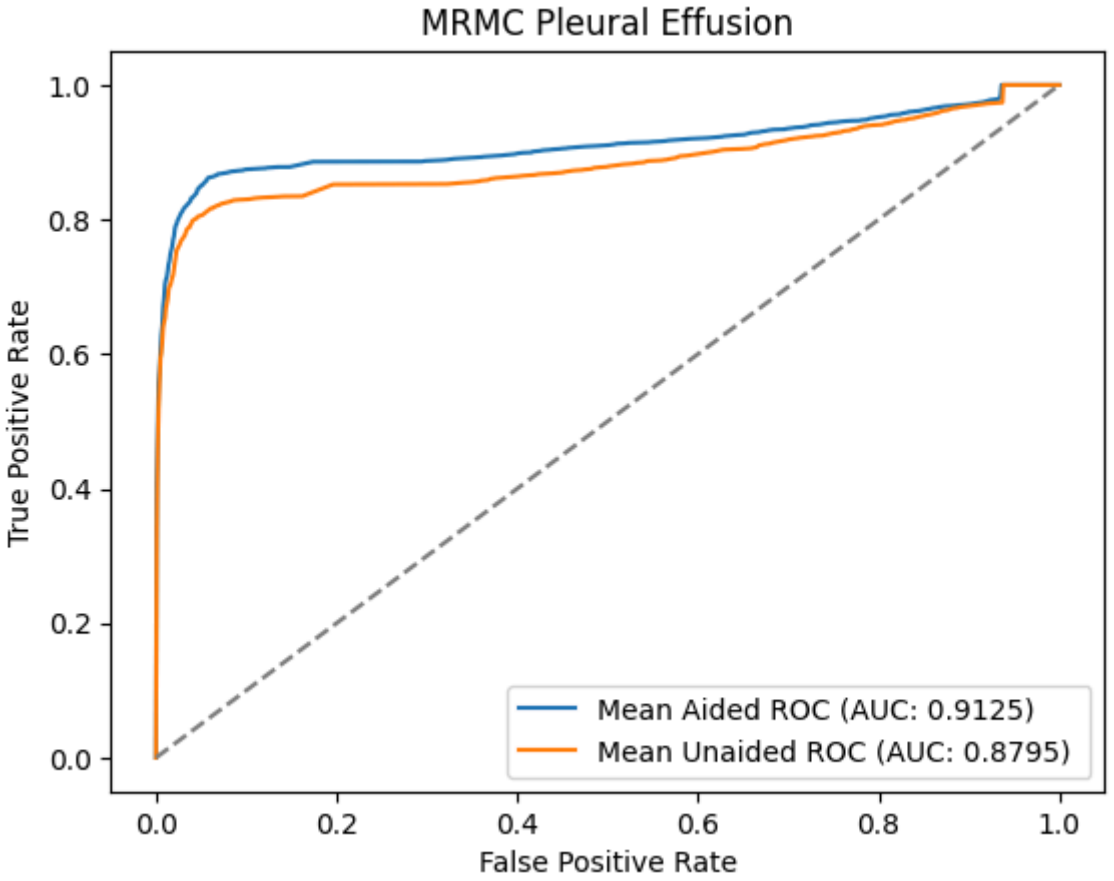
Figure 6: Summary of results of the MRMC study of AZChest for all claimed pathologies in terms of AUC, sensitivity and specificity improvements

- AUC improvement ranges between +0.0318 for increased cardiothoracic ratio (CTR) and +0.0480 for consolidation.
- Sensitivity improvement ranges between +0.0431 for pleural effusion and +0.0695 for consolidation.
- Specificity improvement ranges between +0.0098 for consolidation and +0.0406 for increased cardiothoracic ratio (CTR)

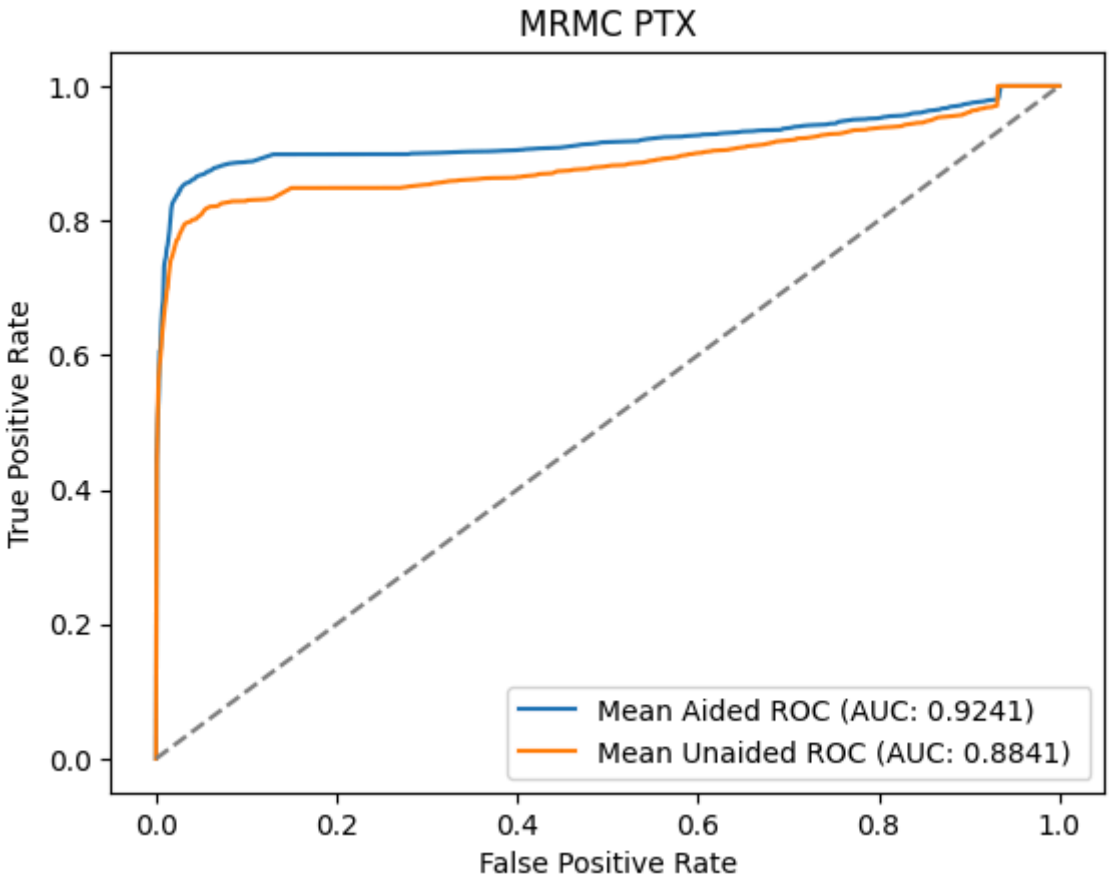
A comparative review of the Multi-Reader Multi-Case (MRMC) study results confirms that Rayvolve AZchest provides an equivalent level of clinical assistance and diagnostic improvement to its users as the legally marketed predicate device, Rayvolve (K260378).

- **Improvement in Diagnostic Accuracy (AUC):** The predicate device demonstrated a significant increase in reader AUC (e.g., from 0.8989 unaided to 0.9451 aided) when diagnosing musculoskeletal dislocations. Similarly, Rayvolve AZchest successfully met its primary objective by demonstrating statistically significant AUC improvements across all four targeted chest pathologies, with gains ranging from +0.0318 (increased cardiothoracic ratio) to +0.0424 (consolidation).
- **Improvement in Sensitivity and Specificity:** The predicate device improved reader sensitivity by approximately +0.065 and specificity by +0.051. Rayvolve AZchest showed highly comparable clinical benefits, boosting reader sensitivity by up to +0.0663 (consolidation) and specificity by up to +0.0406 (increased cardiothoracic ratio), thereby reducing both false negatives and false positives in a clinical setting.
- **Reading Time:** Reading time was reduced by 11.4% to 15.9% for

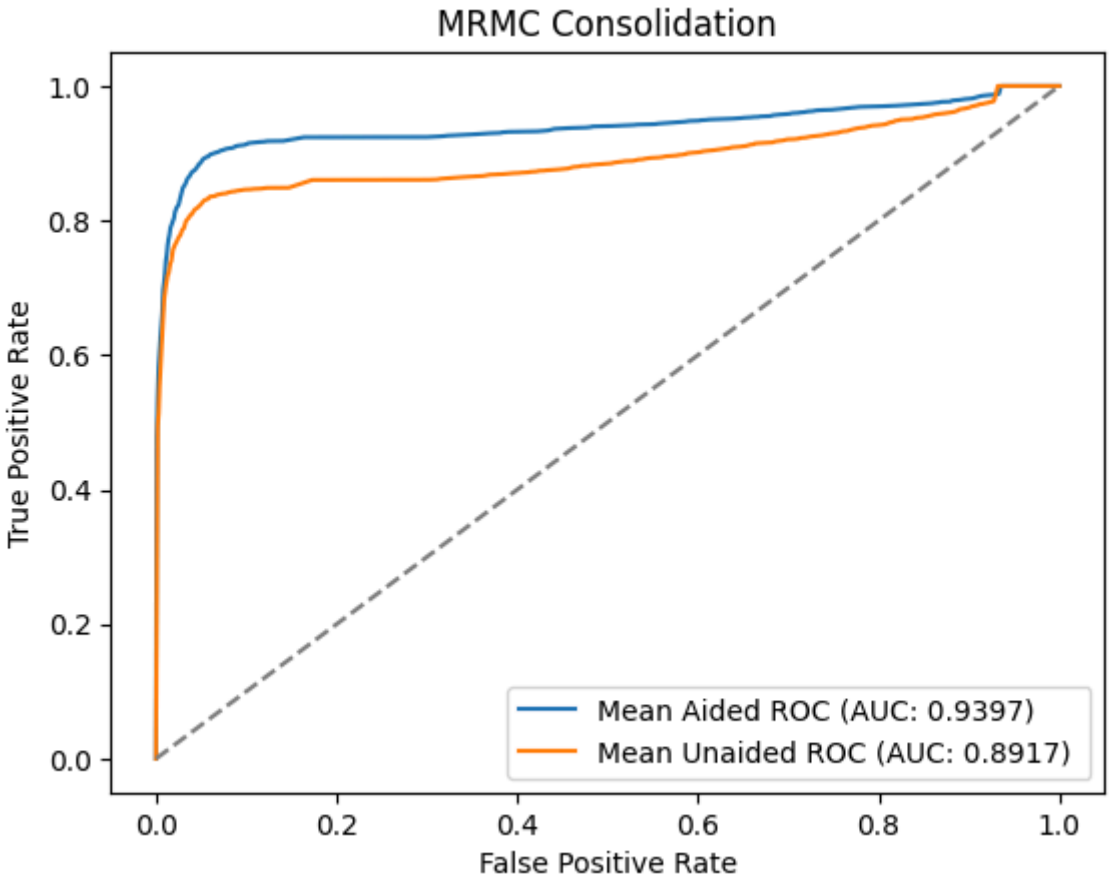
specialists (thoracic radiologists) and by a substantial 24.9% to 31.0% for non-specialists (non-thoracic radiologists).



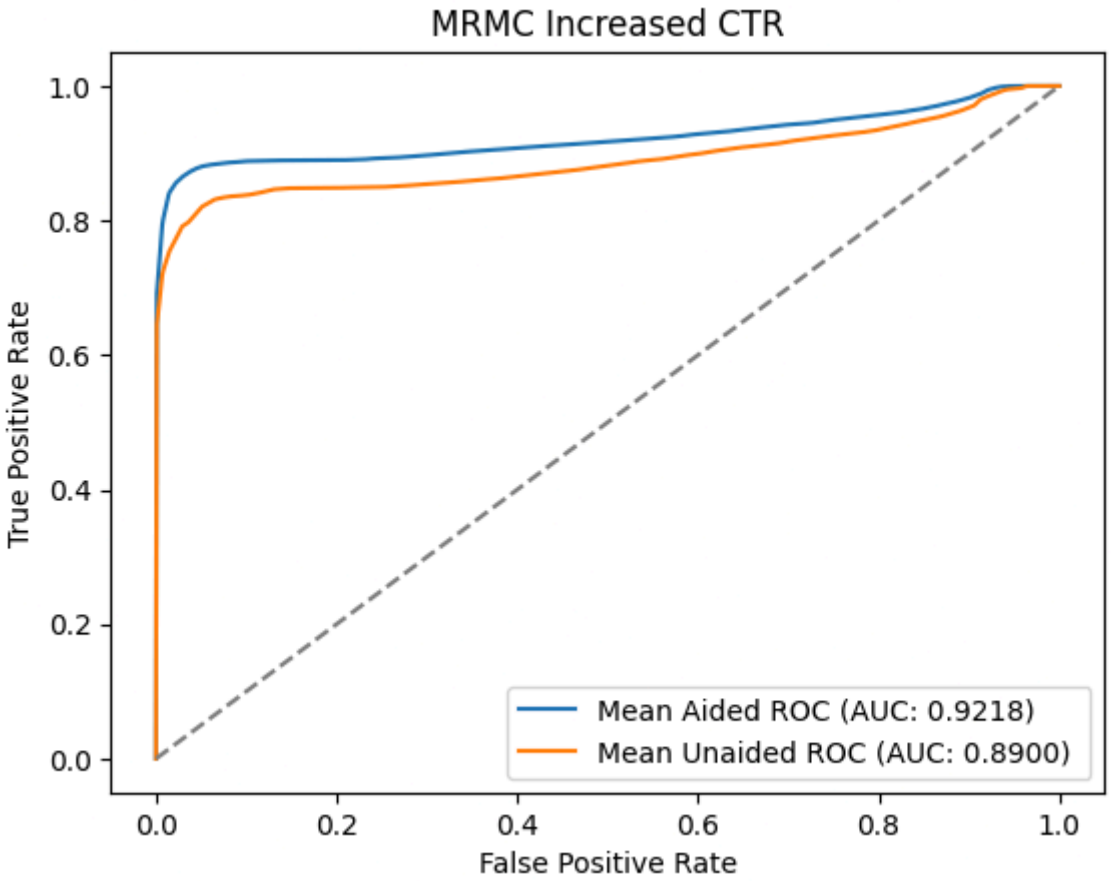
Area Under the Curve (AUC) of the Receiver Operating Characteristic curve (ROC) of the pleural effusion MRMC study (image-level).



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



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



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

Conclusion on Equivalence:

The clinical MRMC data demonstrates that the fundamental clinical effect of improving a radiologist ability to accurately and efficiently diagnose targeted pathologies is identical between the subject and predicate devices. Both devices successfully increase diagnostic accuracy (AUC, Sensitivity, Specificity) while simultaneously decreasing the time required to interpret complex radiographs.

The MRMC results confirm that the transition to thoracic imaging does not introduce new risks of user distraction or diagnostic degradation, thereby supporting the substantial equivalence of Rayvolve AZchest to the predicate device under the 21 CFR 892.2090 (QBS) regulation.

8. Conclusion

Documentation and testing for software and cybersecurity has been provided in accordance with the applicable guidance documents:

- Content of Premarket Submissions for Device Software Functions | FDA
- Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions | FDA

The information and data provided in this submission demonstrate the substantial equivalence of the subject device, Rayvolve AZchest, to the legally marketed predicate device, Rayvolve (K260378).

Both devices share the exact same intended use. They rely on the identical fundamental scientific technology (Supervised Deep Learning), share the same operational workflow, and both share Basic Documentation level.

While the indications for use differ, specifically regarding the targeted anatomical region (Chest vs. Musculoskeletal) and the corresponding clinical findings, these specificities do not alter the core diagnostic assistance purpose of the device.

Comprehensive software verification and validation activities, standalone performance testing, and Multi-Reader Multi-Case (MRMC) clinical studies confirm that Rayvolve AZchest performs safely and effectively according to its specifications. The clinical data proves that the subject device provides highly comparable diagnostic accuracy (AUC, Sensitivity, Specificity) and workflow improvements (reading time reduction) as the predicate device.

Therefore, the differences in the indications for use, as well as the specific UI enhancements (such as contouring for curvilinear findings), do not raise any new or different questions of safety and effectiveness. This clinical and anatomical transition is further supported by the incorporation of GE Critical Care Suite (K223491) as a Reference Device, which validates that providing CADe/x localization outputs on frontal chest radiographs is a well-established, standard, and safely mitigated clinical methodology.

In summary, the subject device, Rayvolve AZchest, is substantially equivalent to the cited predicate device, Rayvolve (K260378).