



March 21, 2025

AZmed
Anthony Joseph
QARA Associate
10 Rue d'Uzès
Paris, 75002
France

Re: K243808

Trade/Device Name: Rayvolve PTX-PE
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: February 17, 2025
Received: February 18, 2025

Dear Anthony Joseph:

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.

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 and is positioned above the printed name.

Jessica Lamb
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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.

K 243808

?

Please provide the device trade name(s).

?

Rayvolve (Rayvolve PTX-PE)

Please provide your Indications for Use below.

?

Rayvolve PTX-PE is a radiological computer-assisted triage and notification software that analyzes chest x-ray images (Postero-Anterior (PA) or Antero-Posterior (AP)) of patients 18 years of age or older for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax).

Rayvolve PTX-PE uses an artificial intelligence algorithm to analyze the images for features suggestive of critical findings and provides study-level output available in DICOM node servers for worklist prioritization or triage.

As a passive notification for prioritization-only software tool within the standard of care workflow, Rayvolve PTX-PE does not send a proactive alert directly to a trained medical specialist.

Rayvolve PTX-PE is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

?

RAYVOLVE PTX-PE
510K Summary

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1. Submitter

Submitted date: 2025-02-17

Submitter	AZmed 10 Rue d'Uzès 75002 Paris, France Phone: +33 6 72 19 04 19
Contact person	Anthony JOSEPH QARA Associate 10 Rue d'Uzès 75002 Paris, France Phone: +33 6 72 19 04 19 Mail: anthony@azmed.co

2. Device identification

Name of the Device	Common or Usual Name	Regulatory section	Classification	Product Code	Panel
Rayvolve PTX-PE	Rayvolve	21 CFR 892.2080	Class II	QFM	90 (Radiology)

3. Predicate device

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

Manufacturer	Product Name	510K Number
Lunit, Inc.	Lunit INSIGHT CXR Triage	K211733



4. Device description

Rayvolve PTX-PE is a software-only device designed to help healthcare professionals. It's a radiological computer-assisted triage and notification software that analyzes chest x-ray images (Postero-Anterior (PA) or Antero-Posterior (AP)) of patients of 18 years of age or older for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). It is intended to work in combination with DICOM node servers.

Rayvolve PTX-PE 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 PTX-PE to interact with existing DICOM node servers (eg.: PACS), and clinical-grade image viewers. The device is designed to run on a cloud platform and be connected to the radiology center's local network. It can also interact with the DICOM Node server.

When remotely connected to a medical center DICOM Node server, the software utilizes AI-based analysis algorithms to analyze chest X-rays for features suggestive of critical findings and provide study-level outputs to the DICOM node server for worklist prioritization. Following receipt of chest X-rays, the software device automatically analyzes each image to detect features suggestive of pneumothorax and/or pleural effusion.

Rayvolve PTX-PE filters and downloads only X-rays with organs determined from the DICOM Node server.

As a passive notification for prioritization-only software tool within the standard of care workflow, Rayvolve PTX-PE does not send a proactive alert directly to a trained health professional. Rayvolve PTX-PE is not intended to direct attention to a specific portion of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

Rayvolve PTX-PE 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 PTX-PE is a radiological computer-assisted triage and notification software that analyzes chest x-ray images (Postero-Anterior (PA) or Antero-Posterior (AP)) of patients of 18 years of age or older for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax).

Rayvolve PTX-PE uses an artificial intelligence algorithm to analyze the images for



features suggestive of critical findings and provides study-level output available in the PACS (or other DICOM storage platforms) for worklist prioritization or triage.

As a passive notification for prioritization-only software tool within the standard of care workflow, Rayvolve PTX-PE does not send a proactive alert directly to a trained medical specialist.

Rayvolve PTX-PE is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

6. Substantial equivalence Discussion

The comparison chart below provides evidence to facilitate the substantial equivalence determination between Rayvolve PTX-PE to the predicate device (K211733) concerning the intended use, technological characteristics, and principle of operation vice and the cited predicate device.

Comparison to predicate device	Lunit INSIGHT CXR Triage - Predicate (K220164)	Rayvolve PTX-PE - Subject device 510(k) file	Comparison to the predicate
Device Name	Lunit INSIGHT CXR Triage	Rayvolve	N/A
Manufacturer	Lunit, Inc.	AZmed	N/A
510 (k) #	K211733	K243808	N/A
Regulation Number	21 CFR 892.2080	21 CFR 892.2080	Same
Class	II	II	Same
Product Code	QFM	QFM	Same
Device Panel	Radiology	Radiology	Same
Level of Concern	Moderate	Moderate	Same
Intended use / Indications for use	Lunit INSIGHT CXR Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings	Rayvolve PTX-PE is a radiological computer-assisted triage and notification software that analyzes chest x-ray images (Postero-Anterior (PA) or Antero-Posterior (AP)) of patients 18 years	Equivalent, slight precision on the intended patient population (see the line 'intended

Comparison to predicate device	Lunit INSIGHT CXR Triage - Predicate (K220164)	Rayvolve PTX-PE - Subject device 510(k) file	Comparison to the predicate
	<p>(pleural effusion and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, Lunit INSIGHT CXR Triage does not send a proactive alert directly to the appropriately trained medical specialists. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.</p>	<p>of age or older for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). Rayvolve PTX-PE uses an artificial intelligence algorithm to analyze the images for features suggestive of critical findings and provides study-level output available in DICOM Node Servers for worklist prioritization or triage. As a passive notification for prioritization-only software tool within the standard of care workflow, Rayvolve PTX-PE does not send a proactive alert directly to a trained medical specialist. Rayvolve PTX-PE is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.</p>	<p>patient population for the justification) and for other DICOM storage platforms the subject device. Other DICOM storage platforms are equivalent to PACS. None of those precisions raise new questions of safety or effectiveness</p>
Intended user	Appropriately trained medical specialists who are qualified to interpret chest radiographs	Healthcare professionals	Equivalent. Healthcare professionals are qualified to interpret chest radiographs
Intended patient population	Adults	18 years of age or older	Equivalent: Our dataset contains images for patients of

Comparison to predicate device	Lunit INSIGHT CXR Triage - Predicate (K220164)	Rayvolve PTX-PE - Subject device 510(k) file	Comparison to the predicate
			<p>18-21 years old. The performance results (see Appendix 25) shows that the performances of Rayvolve PTX-PE for patients between 18 and 21 years old are equivalent to the results obtained for patients older than 21 years old. So, it doesn't raise new questions of safety or effectiveness, and maintain the same level of performance than the predicated device</p>
Targeted clinical condition and anatomy	Pleural effusion, pneumothorax Chest/Lung	Pleural effusion, pneumothorax Chest/Lung	Same
Radiological images format	DICOM	DICOM	Same
Image modality	Frontal chest X-ray	Postero-Anterior (PA) or Antero-Posterior (AP) chest X-ray	Equivalent. Inclusion of the orientation of the image

Comparison to predicate device	Lunit INSIGHT CXR Triage - Predicate (K220164)	Rayvolve PTX-PE - Subject device 510(k) file	Comparison to the predicate
			acquisition, but the performance testing (see appendix 25) has demonstrated that Rayvolve PTX-PE achieves equivalent accuracy on both AP and PA views, so considering both views doesn't raise new questions of safety or effectiveness, and maintain the same level of performance than the predicated device
Algorithm for pre-specified critical findings detection	AI algorithm designed to detect pleural effusion and pneumothorax in chest X-ray images. Lunit INSIGHT CXR Triage uses a vendor agnostic algorithm compatible with DICOM chest X-ray images.	AI algorithm designed to detect pleural effusion and pneumothorax in chest X-ray images. Rayvolve PTX-PE uses a vendor agnostic algorithm compatible with DICOM chest X-ray images.	Same
Where generated results are stored	PACS/Workstation	PACS/Workstation	Same

Comparison to predicate device	Lunit INSIGHT CXR Triage - Predicate (K220164)	Rayvolve PTX-PE - Subject device 510(k) file	Comparison to the predicate
Computational platform	Lunit INSIGHT CXR Triage is designed as a software module that can be deployed on several computing and X-ray imaging platforms such as radiological imaging equipment, PACS, On Premise or On Cloud.	Rayvolve PTX-PE is designed as a software module that can be deployed on several computing and X-ray imaging platforms such as radiological imaging equipment, PACS, On Premise or On Cloud.	Same
Device output in case of positive detection	<p>When deployed on other radiological imaging equipment Lunit INSIGHT CXR Triage automatically runs after image acquisition and prioritizes and displays the analysis result through the worklist interface of PACS/workstation.</p> <p>No markup on original image. Secondary capture of the finding.</p> <p>Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems), an on-device, technician notification indicating which cases were flagged by Lunit INSIGHT CXR Triage in PACS, is generated 15 minutes after interpretation by the user.</p> <p>The on device notification is contextual and does not provide any diagnostic</p>	<p>When deployed on other radiological imaging equipment Rayvolve PTX-PE automatically runs after image acquisition and prioritizes and displays the analysis result through the worklist interface of PACS/workstation.</p> <p>No markup on the original image. Secondary capture of the device will indicate the presence of findings suspicious of pneumothorax or pleural effusion.</p> <p>Upon image acquisition from other radiological imaging equipment (e.g, X-ray systems), a passive notification indicating which studies were flagged by Rayvolve PTX-PE is generated.</p> <p>The notification is</p>	Same

Comparison to predicate device	Lunit INSIGHT CXR Triage - Predicate (K220164)	Rayvolve PTX-PE - Subject device 510(k) file	Comparison to the predicate
	information. It is not intended to inform any clinical decision, prioritization, or action to the technologist.	contextual and does not provide any diagnostic information. It is not intended to inform any clinical decision, prioritization, or action.	
Notification (i.e., recipient timing and means of notification)	Passive notification. Images with suspicion of pleural effusion and/or pneumothorax are flagged in PACS/workstation	Passive notification. Images with suspicion of pneumothorax and/or pleural effusion are flagged in PACS/workstation/DICOM viewer.	Equivalent: DICOM viewers are the software that allow to open the Dicom files on the workstations, it doesn't raise new questions of safety or effectiveness
Performance level - Timing of notification	The average time taken by the device to analyze the study and send a notification to the worklist is 20,76 seconds for pleural effusion and 20.45 seconds for pneumothorax	The average time taken by the device to analyze the study and send a notification to the worklist is 19.56 seconds for pleural effusion and 19.43 seconds for pneumothorax	Equivalent The performance results of the subject device are slightly better than the results for the predicate device, so it doesn't raise new questions of safety or effectiveness.
Performance level - accuracy of classification	Pleural Effusion ROC AUC > 0.95 AUC: 0.9686 (95% CI: [0.9547,0.9824]) Sensitivity 89.86% (95% CI: [86.72, 93.00])	Pleural Effusion ROC AUC > 0.95 AUC: 0.9830 (95% CI: [0.9778, 0.9880]) Sensitivity 0.9134 (95% CI: [0.8874, 0.9339])	Equivalent The performance results of the subject device are slightly better than the

Comparison to predicate device	Lunit INSIGHT CXR Triage - Predicate (K220164)	Rayvolve PTX-PE - Subject device 510(k) file	Comparison to the predicate
	Specificity 93.48% (95% CI: [91.06, 95.91]) Pneumothorax ROC AUC > 0.95 AUC: 0.9630 (95% CI: [0.9521,0.9739]) Sensitivity 88.92% (95% CI: [85.60,92.24]) Specificity 90.51% (95% CI: [88.18,92.83])	Specificity 0.9448 (95% CI: [0.9239, 0.9339]) Pneumothorax ROC AUC > 0.95 AUC: 0.9857 (95% CI: [0.9809,0.9901]) Sensitivity 0.9379 (95% CI: [0.9127,0.9561]) Specificity 0.9178 (95% CI: [0.8911,0.9561])	results for the predicate device, so it doesn't raise new questions of safety or effectiveness.

Table 1: Comparison between predicate and subject devices

AZmed claims the substantial equivalence of Rayvolve PTX-PE with the predicate Lunit INSIGHT CXR Triage (K211733) based on the **functional principle** of the software algorithms, the **same technological characteristics**, and the **intended use** of the software.

7. Performance data summary

a. Software verification and validation testing

The device's software development, verification and validation have been carried out in accordance with FDA guidelines. The software was tested against the established software design specification for each test plan to assure the device performances as intended. The device hazard analysis was completed and risk control 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 PTX-PE 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

AZmed conducted a standalone performance assessment for Pneumothorax and Pleural Effusion in worklist prioritization and triage.

The clinical performance is evaluated considering the following factors:

- The interpretative process is a concurrent read
- The physical characteristic of Rayvolve PTX-PE mark is a header containing information on the presence or absence of a pathology, known as Pneumothorax or Pleural Effusion.
- The users are healthcare professionals

The sample size was composed of 1000 radiographs in the Pneumothorax group and 1000 radiographs in the Pleural effusion group. Positive and negative images represent 50% of the sample (+/- 5%).

The results of the standalone study demonstrated that Rayvolve PTX-PE :

- Detects pneumothorax with high sensitivity (0.9379, 95% Confidence interval (CI): 0.9127; 0.9561), high specificity (0.9178, 95% Confidence interval (CI): 0.8911; 0.9561) and high area under the Curve (AUC) of the Receiver Operating Characteristic (ROC) (0.9857, 95% Confidence Interval (CI): 0.9809; 0.9901) and with a performance time of 19.43 seconds (95% CI: 19.42 - 19.45)
- Detects pleural effusion with high sensitivity (0.9134, 95% Confidence Interval (CI): 0.8874; 0.9339), high specificity (0.9448, 95% Confidence Interval (CI): 0.9239; 0.9339) and high area under the Curve (AUC) of the Receiver Operating Characteristic (ROC) (0.9830, 95% Confidence Interval (CI): 0.9778; 0.9880) and with a performance time of 19.56 seconds (95% CI: 19.49 - 19.58)

The results of the standalone study demonstrated that Rayvolve PTX-PE detects pneumothorax and pleural effusion with high AUC, sensitivity, and specificity for all the following variables: age, gender, ethnicity, device projection views, patient position (upright or supine), institutions, and additional conditions.

8. CONCLUSION

Both the subject device (Rayvolve PTX-PE) and the predicated device are computer-assisted triage and notification software that analyzes frontal chest x-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). They both accept as input radiographs in DICOM format, use AI algorithms to detect pleural effusion and pneumothorax in chest X-rays and send back the same type of output and notifications in case of positive detection. The differences in the indication for use, including the differences in the patient



population, the difference in the intended users, and the precision in the image modality for the subject device, do not raise different questions of safety and effectiveness. The results of the standalone performance assessment demonstrate that Rayvolve PTX-PE performs according to the specifications and meets user needs and intended use.

Therefore, Rayvolve PTX-PE and the predicate Lunit INSIGHT CXR Triage (K211733) are substantially equivalent.