March 26, 2025

AZmed
℅ Christelle Baille
Head of QARA
10 Rue d'Uzès
PARIS, 75002
FRANCE

Re: K243831
Trade/Device Name: Rayvolve LN
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: February 17, 2025
Received: February 18, 2025

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.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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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)*
K243831

Device Name
Rayvolve LN

Indications for Use *(Describe)*
Rayvolve LN is a computer-aided detection software device to assist radiologists to identify and mark regions in relation to suspected pulmonary nodules from 6 to 30mm size. It is designed to aid radiologists in reviewing the frontal (AP/PA) chest radiographs of patients of 18 years of age or older acquired on digital radiographic systems as a second reader and be used with any DICOM Node server. Rayvolve LN provides adjunctive information only and is not a substitute for the original chest radiographic image.

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)

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RAYVOLVE LN
510K Summary

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Content

1. Submitter

Submitted date: 2025-03-24

Submitter	AZmed SAS 10 rue d'Uzès 75002 Paris **Phone:** +33 6 43 31 51 38
Contact personn	Christelle BAILLE Head of QARA 10 rue d'Uzès 75002 Paris **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 LN	Rayvolve	21 CFR 892.2070	Class II	MYN	90 (Radiology)

3. Predicate device

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

Manufacturer	Brand Name	Commercial Name	510K Number
Samsung Electronics Co., Ltd.	Auto Lung Nodule Detection	Auto Lung Nodule Detection	K201560

4. Device description

The medical device is called Rayvolve LN. Rayvolve LN is one of the verticals of the Rayvolve product line. It is a standalone software that uses deep learning techniques to detect and localize pulmonary nodules on chest X-rays. Rayvolve LN is intended to be used as an aided-diagnosis device and does not operate autonomously.

Rayvolve LN 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 LN 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 LN directly interacts with the DICOM files to output the prediction (potential presence of pulmonary nodules) the original image appears first, followed by the image processed by Rayvolve.

Rayvolve LN 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 LN's use.

5. Intended use/Indication for use

Rayvolve LN is a computer-aided detection software device to assist radiologists to identify and mark regions in relation to suspected pulmonary nodules from 6 to 30mm size. It is designed to aid radiologists in reviewing the frontal (AP/PA) chest radiographs of patients 18 years of age or older acquired on digital radiographic systems as a second reader and be used with any DICOM Node server. Rayvolve LN provides adjunctive information only and is not a substitute for the original chest radiographic image.

6. Substantial equivalence Discussion

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

Comparison to predicate device	Predicate - Auto Lung Nodule Detection (K201560)	Rayvolve LN - Subject device 510(k) file
Device Name	Auto Lung Nodule Detection	Rayvolve
Manufacturer	Samsung Electronics Co., Ltd.	AZmed SAS
510 (k) #	K201560	K243831
Regulation Number	21 CFR 892.2070	21 CFR 892.2070
Class	II	II

Comparison to predicate device	Predicate - Auto Lung Nodule Detection (K201560)	Rayvolve LN - Subject device 510(k) file
Regulation Description	Medical Image Analyser	Medical Image Analyser
Product Code	MYN	MYN
Device Panel	Radiology	Radiology
Level of Concern	Moderate	Moderate
Intended use / Indications for use	The Auto Lung Nodule Detection is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 10 to 30 mm in size. It is designed to aid the physician to review the PA chest radiographs of adults as a second reader and be used as part of S-Station, which is operation software installed on Samsung Digital X-ray Imaging systems. Auto Lung Nodule Detection cannot be used on the patients who have lung lesions other than abnormal nodules.	Rayvolve LN is a computer-aided detection software device to assist radiologists to identify and mark regions in relation to suspected pulmonary nodules from 6 to 30mm size. It is designed to aid radiologists in reviewing the frontal (AP/PA) chest radiographs of patients of 18 years of age or older, acquired on digital radiographic systems as a second reader and be used with any DICOM Node server. Rayvolve LN provides adjunctive information only and is not a substitute for the original chest radiographic image.
Target population	Physician	Radiologists
Intended User Workflow	Device intended as a second-reader for physicians interpreting chest radiographs	Device intended as a second-reader for physicians interpreting chest radiographs
Intended patient population	Adult population	Patients 18 years of age or older
Image modality	X-ray	X-ray
Anatomical site	Chest	Chest

Comparison to predicate device	Predicate - Auto Lung Nodule Detection (K201560)	Rayvolve LN - Subject device 510(k) file
Clinical findings	Lung Nodules on PAview Chest X-rays	Lung Nodules on PA/AP view Chest X-rays
Machine learning technology	Machine learning	Supervised Deep learning
Input format	DICOM	DICOM
Output	ROI marked on the duplicated input image	ROI marked on the duplicated input image
Biocompatibility / electromagnetic / magnetic resonance / Electrical/mechanical / chemical / thermal / radiation/ steriliy safety	N/A, the device is a standalone software/	N/A, the device is a standalone software/
Reader workflow	Second reader workflow	Second reader workflow

Table 1: Comparison between the predicate and subject devices

Rayvolve LN and Samsung Auto Lung Nodule Detection both analyze chest radiographs to detect and localize pulmonary nodules, returning regions of interest (ROIs) on a secondary DICOM and acting as a second reader for radiologists on chest X-rays, with algorithms that function similarly to detect and mark nodules. Both technologies fall under the broader category of artificial intelligence (AI) and aim to achieve the same clinical objective: identifying and marking pulmonary nodules on chest radiographs. The predicate device detects nodules sized 10-30mm, whereas Rayvolve LN can detect and mark nodules sized 6-30mm. This difference in size range does not impact performance, as testing demonstrates equivalent accuracy in both devices. Additionally, Rayvolve LN supports both AP and PA views. AP views are clinically relevant in scenarios such as bedside radiography for critically ill patients or patients unable to stand for a PA view. These views provide similar diagnostic content, specifically for detecting pulmonary nodules. Performance testing has demonstrated that Rayvolve LN achieves equivalent accuracy in detecting lung nodules on both AP and PA views. This ensures that the inclusion of AP views does not introduce new safety or effectiveness concerns, maintaining the same level of performance as the predicate device.

The intended users of Rayvolve LN are radiologists.

Performance and clinical testing were performed to support the safety and effectiveness of the technological differences between Rayvolve LN and the

predicate device. The results of these tests demonstrate that Rayvolve LN has been designed and tested to conform to its intended use and comparably to the predicate device. Both devices share the same technology, intended use, and clinical objective, and the data confirms that our device is substantially equivalent to the predicate, ensuring no differences in safety or effectiveness.
Differences between both products do not present any new safety or effectiveness concerns. As such, it can be considered substantially equivalent to the predicate devices.
In summary, both devices share the same technology, intended use, and clinical objective, and the supporting data demonstrates that Rayvolve LN performs equivalently to the predicate device, ensuring no differences in safety or effectiveness.

7. Performance data

a. Software verification and validation testing

The device's software development, verification, and validation have been carried out following recommendations in FDA's software guidance. 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 LN device passes all the testing and supports the claims of substantial equivalence with the predicate.

Validation activities included a usability study of Rayvolve LN 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 on 2181 radiographs for all the study types and views in the indication for use. The results of standalone testing at image level demonstrated that Rayvolve LN detects pulmonary nodules with sensitivity (0.8847, 95% Wilson's Confidence Interval (CI): 0.8638; 0.9028), specificity (0.8294; 95% Wilson's CI: 0.8066; 0.9028) and Area Under The Curve (AUC) of the Receiver Operating Characteristic (ROC) (0.8408; 95% Bootstrap CI: 0.8272; 0.8548).
Subgroup analyses (AUC, sensitivity, and specificity) were performed to assess the device's performance across the following variables: age, gender, ethnicity, machine of acquisition, radiograph views, institution, position of acquisition, presence of simple or multi-nodules, size of nodules, density of nodules, and location of nodules.

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c. Clinical data

AZmed conducted a fully crossed multiple readers, multiple case (MRMC) retrospective reader study to determine the impact of Rayvovle LN on reader performance in diagnosing pulmonary nodules on chest radiographs.

The primary objective of this MRMC study was to determine whether the diagnostic accuracy of readers aided by Rayvolve LN was superior to reader accuracy when unaided by Rayvolve LN, as determined by the AUC of the ROC curve. The secondary objective was to report the sensitivity and specificity per image of Rayvolve LN aided and unaided reads, and the Alternative Free Response Receiver Operating Characteristic (AFROC), False Positives Per Image and sensitivity per nodule of Rayvolve LN aided and unaided reads.
Time was evaluated per-user performance and per-specialty performance at image level.

The readers (radiologists) evaluated cases under aided and unaided conditions. The cases are randomly sampled from the validation dataset used for the standalone performance study, to provide ground truth binary labeling indicating the presence or absence of pulmonary nodules. 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 asked to draw, if a nodule is present on the radiograph displayed on the viewer, the smallest rectangular area possible around the nodule.

In addition to this binary decision of the readers regarding the presence or absence of nodule, each reader provided a confidence score with an ordinal value.

The study demonstrated an improvement in the performance of readers when aided by Rayvolve LN as measured by the AUC of the ROC:

- Reader AUC improved from 0.8071 to 0.8583 (a difference of 0.0511) (95% CI: 0.0501; 0.0518), across the 400 cases within Rayvolve LN ’s Indications for Use.
- Reader sensitivity per image was significantly improved from 0.7975 (95% CI: 0.7848; 0.8097) to 0.8935 (95% CI: 0.8836; 0.9027)
- Reader specificity per image was improved from 0.8235 (95% CI: 0.8114; 0.8350) to 0.8510 (95% CI: 0.8396; 0.9027)

Rayvolve LN -aided and Rayvolve LN -unaided AUC (and sensitivity, specificity) results were broken down by relevant confounders (gender, age, imaging device used to acquire radiographs).

The study demonstrated consistent improvement of performance across metrics and confounders in Rayvolve LN-aided reads as compared to Rayvolve LN-unaided reads.

8. CONCLUSION

Rayvolve LN and the predicate device (Auto Lung Nodule Detection) are computer-aided detection software devices to assist radiologists in identifying and marking regions in relation to suspected pulmonary nodules. They accept radiographs in DICOM format and use machine learning techniques to process the images.

The performance and clinical testing demonstrate that Rayvolve LN performs comparably to the predicate device, showing similar performance in key metrics such as nodule-level specificity. These results indicate that Rayvolve LN is as effective as the predicate device, with no new safety or effectiveness concerns arising from the technological differences.

Overall, Rayvolve LN and the predicate device share the same technology, intended use, and clinical objective. The data confirm that Rayvolve LN is substantially equivalent to the predicate, ensuring no differences in safety, performance, or effectiveness.