March 21, 2024

Siemens Healthcare GmbH
c/o Kira Morales
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
MALVERN, PA 19335

Re: K233753
Trade/Device Name: AI-Rad Companion (Pulmonary)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, QIH
Dated: February 20, 2024
Received: February 20, 2024

Dear Kira Morales:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

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

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.

Submission Number *(if known)*

K233753

Device Name

AI-Rad Companion (Pulmonary)

Indications for Use *(Describe)*

AI-Rad Companion (Pulmonary) is image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from specialty care and general practice in the evaluation and assessment of disease of the lungs.
It provides the following functionality:
• Segmentation and measurements of complete lung and lung lobes
• Identification of areas with lower Hounsfield values in comparison to a predefined threshold for complete lung and lung lobes
• Providing an interface to external Medical Device syngo.CT Lung CAD
• Segmentation and measurements of solid and sub-solid lung nodules
• Dedication of found lung nodules to corresponding lung lobe
• Correlation of segmented lung nodules of current scan with known priors and quantitative assessment of changes of the correlated data.
• Identification of areas with elevated Hounsfield values, where areas with elevated versus high opacities are distinguished.

The software has been validated for data from Siemens Healthineers (filtered backprojection and iterative reconstruction), GE Healthcare (filtered backprojection reconstruction), and Philips (filtered backprojection reconstruction).

Only DICOM images of adult patients are considered to be valid input.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
FOR
AI-RAD COMPANION (Pulmonary)
SW version VA40

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: March 18, 2024

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. Submitter

Importer/Distributor

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40 Liberty Boulevard
Malvern, PA 19355
Registration Number: 2240869

Manufacturing Site

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2. Contact Person

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3. Device Name and Classification

Product Name:	AI-Rad Companion (Pulmonary)
Trade Name:	AI-Rad Companion (Pulmonary)
Classification Name:	Computed Tomography X-Ray System

Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Secondary CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	JAK
Secondary Product Code:	QIH

4. Predicate Device

Product Name:	AI-Rad Companion (Pulmonary)
Propriety Trade Name:	AI-Rad Companion (Pulmonary)
510(k) Number:	K213713
Clearance Date:	August 11, 2022
Classification Name:	Computed Tomography X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Secondary CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	JAK
Secondary Product Code:	QIH
Recall Information:	N/A

5. Indications for Use

AI-Rad Companion (Pulmonary) is image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from specialty care and general practice in the evaluation and assessment of disease of the lungs.

It provides the following functionality:

- Segmentation and measurements of complete lung and lung lobes
- Identification of areas with lower Hounsfield values in comparison to a predefined threshold for complete lung and lung lobes
- Providing an interface to external Medical Device syngo.CT Lung CAD
- Segmentation and measurements of solid and sub-solid lung nodules
- Dedication of found lung nodules to corresponding lung lobe
- Correlation of segmented lung nodules of current scan with known priors and quantitative assessment of changes of the correlated data.
- Identification of areas with elevated Hounsfield values, where areas with elevated versus high opacities are distinguished.

The software has been validated for data from Siemens Healthineers (filtered backprojection and iterative reconstruction), GE Healthcare (filtered backprojection reconstruction), and Philips (filtered backprojection reconstruction).

Only DICOM images of adult patients are considered to be valid input.

Modified Indications for Use Assessment

The Indications for Use for AI-Rad Companion (Pulmonary) VA40 was updated to introduce the sub-solid lung nodule segmentation feature compared to the predicate. Additionally, the removal of the intended users "emergency medicine" and "urgent care" physicians was a clarification to further align with the intended user profiles and the risk analysis. The Indications for Use statement has been modified to provide a more accurate description of the extension's functionality but does not represent a new intended use in comparison to the predicate.

6. Device Description

The subject device AI-Rad Companion (Pulmonary) is an image processing software that utilizes machine learning and deep learning algorithms to provide quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support qualified clinicians in the evaluation and assessment of disease of the thorax. AI-Rad Companion (Pulmonary) builds on platform functionality provided by the AI-Rad Companion Engine and cloud/edge functionality provided by the Siemens Healthineers teamplay digital platform. AI-Rad Companion (Pulmonary) is an adjunct tool and does not replace the role of a qualified medical professional. AI-Rad Companion (Pulmonary) is also not designed to detect the presence of radiographic findings other than the prespecified list. Qualified medical professionals should review original images for all suspected pathologies.

AI-Rad Companion (Pulmonary) offers:

- Segmentation of lungs,
- Segmentation of lung lobes,
- Parenchyma evaluation,
- Parenchyma ranges,
- Pulmonary density,
- Visualization of segmentation and parenchyma results,
- Interface to LungCAD,
- Lesion segmentation,
- Visualization of lesion segmentation results,
- Lesion follow-up

AI-Rad Companion (Pulmonary) requires images of patients of 22 years and older.

AI-Rad Companion (Pulmonary) SW version VA40 is an enhancement to the previously cleared device AI-Rad Companion (Pulmonary) (K213713) that utilizes machine and deep learning algorithms to provide quantitative and qualitative analysis to computed tomography DICOM images to support qualified clinicians in the evaluation and assessment of disease of the thorax.

As an update to the previously cleared device, the following modifications have been made:

- Sub-solid Lung Nodule Segmentation

This feature provides the ability to segment and measure all subtypes of lesions including solid and sub-solid lesions.

- Modified Indications for Use Statement
  The indications for use statement was updated to include descriptive text for sub-solid lung nodule addition.

- Updated Subject Device Claims List
  The claims list was updated to reflect the new device functionality

- Updated Limitations for Use
  Additional limitations for use has been added to the subject device.

7. Technological Characteristics

The comparison between the above referenced predicate device are listed at a high-level in the following table.

Feature	Subject Device AI-Rad Companion (Pulmonary) VA40	Predicate Device AI-Rad Companion (Pulmonary) (K213713)	Comparison Results
Modality	CT	CT	Identical
Segmentation of lungs	Creation of a lung segmentation mask by combining the segmentation masks of 5 lung lobes.	Creation of a lung segmentation mask by combining the segmentation masks of 5 lung lobes.	Identical
Segmentation of lung lobes	Computation of segmentation masks of the five lung lobes (right upper (RUL), right middle (RML), right lower (RLL), left upper (LUL) and left lower (LLL) lobe) for a given CT data set of the chest.	Computation of segmentation masks of the five lung lobes (right upper (RUL), right middle (RML), right lower (RLL), left upper (LUL) and left lower (LLL) lobe) for a given CT data set of the chest.	Identical
Parenchyma evaluation	The parenchyma evaluation uses the lobe mask, counts all voxels per lobe, counts image voxels below -950 HU, and calculates the percentages of these voxels relative to the total number of voxels. Additionally, it sums the individual lobe results and calculates the percentage for the complete lung.	The parenchyma evaluation uses the lobe mask, counts all voxels per lobe, counts image voxels below -950 HU, and calculates the percentages of these voxels relative to the total number of voxels. Additionally, it sums the individual lobe results and calculates the percentage for the complete lung.	Identical
Parenchyma Ranges	The percentages are likewise dedicated to the 4 ranges. Name of ranges and their ranges are configurable by the user.	The percentages are likewise dedicated to the 4 ranges. Name of ranges and their ranges are configurable by the user.	Identical

Pulmonary Density	AI-based identification of areas with elevated Hounsfield values. Threshold-based identification of highest elevated Hounsfield values inside these elevated regions, by a predefined threshold of -200 HU	AI-based identification of areas with elevated Hounsfield values. Threshold-based identification of highest elevated Hounsfield values inside these elevated regions, by a predefined threshold of -200 HU	Identical
Visualization of segmentation and parenchyma results	Color overlay of MPR and VRT with evaluation results	Color overlay of MPR and VRT with evaluation results	Identical
Interface to LungCAD	Interface to syngo.CT LungCAD	Interface to syngo.CT LungCAD	Identical
Lesion segmentation	Segmentation of solid and sub-solid lung lesions including the following data: • Relative change of maximum 2D diameter [%] • relative change of maximum orthogonal 2D diameter [%] • relative change of mean 2D diameter [%], • relative change of maximum 3D diameter [%] • Relative change of volume (volume doubling time [d], negative growth [%])	Segmentation of lung lesions including the following data: • Relative change of maximum 2D diameter [%] • relative change of maximum orthogonal 2D diameter [%] • relative change of mean 2D diameter [%], • relative change of maximum 3D diameter [%] • Relative change of volume (volume doubling time [d], negative growth [%])	Enhanced – addition of sub-solid lesion segmentation
Visualization of lesion segmentation results	Color overlay of MPR and VRT with evaluation	Color overlay of MPR and VRT with evaluation	Identical
Lesion follow-up	Correlation of segmented lung lesions with known priors using the data from the lesion segmentation.	Correlation of segmented lung lesions with known priors using the data from the lesion segmentation.	Identical
Deployment	Cloud and Edge (on-premise) deployments	Cloud and Edge (on-premise) deployments	Identical

Table 1: Technological Comparisons

8. Nonclinical Tests

Non-clinical tests were conducted to test the functionality of AI-Rad Companion (Pulmonary). Software validation and bench testing have been conducted to assess the performance claims as well as the claim of substantial equivalence to the predicate device.

AI-Rad Companion has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrates that AI-Rad Companion (Pulmonary) complies with the FDA guidance document, "Guidance for the Content of Premarket Submissions for Device Software Functions" (June 14, 2023) as well as with the following voluntary FDA recognized Consensus Standards listed in **Table 1** below.

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
5-129	General	Medical Devices – Application of usability engineering to medical devices [including Corrigendum 1 (2016)]	62366-1: 2020-06	IEC
5-125	General	Medical Devices – application of risk management to medical devices	14971 Third Edition 2019-12	ISO
13-79	Software/ Informatics	Medical device software – software life cycle processes [Including Amendment 1 (2016)]	62304 Edition 1.1 2015-06 Consolidated	IEC
12-349	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 2022d	NEMA
5-134	Radiology	Medical devices – symbols to be used with information to be supplied by the manufacturer	15223-1 Fourth Edition 2021-07	ISO

Table 2: Voluntary Conformance Standards

Verification and Validation

Non-clinical tests were conducted on the subject device during product development. Software "bench" testing in the form of Unit, System and Integration tests were performed to evaluate the performance and functionality of the new features and software updates. All testable requirements in the Requirement Specifications and the Risk Analysis have been successfully verified and traced in accordance with the Siemens Healthineers DH product development (lifecycle) process. Human factor usability validation is addressed in system testing and usability validation test records. Software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans.

Siemens Healthineers adheres to the cybersecurity requirements as defined the FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (September 27, 2023) by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient.

9. Performance Software Validation

To validate AI-Rad Companion (Pulmonary) VA40 software from a clinical perspective, the lesion segmentation algorithm underwent a scientific evaluation. The results of clinical data-based software validation for the subject device, AI-Rad Companion (Pulmonary)VA40, demonstrated substantially equivalent performance in comparison to the predicate device. The performance of the sub-solid lesion segmentation algorithm was analyzed against the predicate's performance of solid nodule segmentation. The additional features of AI-Rad Companion (Pulmonary) were unchanged from the predicate and did not undergo a new scientific evaluation.

Performance testing for AI-Rad Companion (Pulmonary) lesion segmentation algorithm was performed on multiple vendor test data from 273 subjects in the United States and 254 subjects in Germany.

Acceptance Criteria:

Validation Type	Target
Failure Rate	< 1%
Accuracy for Solid & Calcified nodules	Average DICE ≥ predicate Bias & RMSE ≤ predicate LoA in line with predicate LoA
Accuracy for sub-solid nodules	Performance was analyzed in relation to the predicate's solid nodule segmentation performance Median nodule size range for sub-solid is 10mm-20mm LoA for 10mm-20mm ≥ 95% for all three diameter metrics
DICE score	Average DICE score for sub-solid nodules ≥ average DICE for predicate solid nodules
Consistency of Subgroup results	Average DICE not smaller than DICE of overall cohort minus 1 STD Bias of three metrics not exceed ±1 STD RMSE of three metrics not exceed RMSE of overall cohort +1 STD each

Table 3: Acceptance Criteria for Subject Device Performance

Testing Data Information:

Category	Frequency
Manufacturer	Canon/Toshiba: 18 GE: 35 Philips: 15 Siemens: 32

Data Origin	US: 69 Germany: 31
Dose	Low: 31 Conventional: 69
Contrast Enhancement	Contrasted: 47 Native: 53
Slice Thickness [mm]	≤1.25: 37 (1.25-2]: 25 (2-3]: 38
Age group [years]	[21-40): 17 [40-60): 28 [60-70): 24 [70-80): 21 ≥80: 10
Nodule type	Solid: 90 Calcified: 12 Sub-solid: 98
Nodule Size Range [mm]	[3-6): 25 [6-10): 22 [10-20): 33 [20-30]: 7
Patient Sex	Male: 47 Female: 53

Table 4: Testing Data Characteristics for subject device

Testing Summary

AI-Rad Companion (Pulmonary) VA40 performed significantly better than the predicate device (K213713). For the existing solid and calcified nodule types and sizes, the average DICE coefficient was greater than that of the predicate. For sub-solid nodules, the average DICE coefficient of the subject device was superior to the average DICE coefficient of the predicate device for solid nodules. The subject device also met its individual subgroup analysis acceptance criterion for all subgroups.

Standard Annotation Process:

For the testing data the ground truth annotations were established independently by two board certified radiologists (10 and 7 years of experience, respectively). In case of disagreement a third radiologist (9 years of experience) served as an adjudicator.

Testing & Training Data Independence:

None of the clinical sites providing the test data provided data for training of any of the algorithms. Therefore there is a clear independence on site level between training and test data.

10. Summary of Nonclinical Tests

Based on the nonclinical performance documented within the Scientific Evaluation, AI-Rad Companion (Pulmonary) VA40 was found to substantially equivalent to the predicate. Since the predicate device was cleared based on the results of the prior conducted scientific evaluation, the same methodology was required to support the substantial equivalence. The nonclinical data and verification and validation results supports the substantial equivalence of the subject device in that it performs as well as or better than to the predicate device that is currently marketed.

11. Summary Clinical Tests

The predicate (K213713) was not validated using clinical tests and therefore no clinical tests were conducted to test the performance and functionality of the modifications introduced within AI-Rad Companion (Pulmonary). Verification and validation of the enhancements and improvements have been performed and these modifications have been validated for their intended use. The data from these activities were used to support the subject device and the substantial equivalence argument. No animal testing has been performed on the subject device.

12. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device.

Risk management is ensured via ISO 14971:2019 compliance to identify and provide mitigation of potential hazards in a risk analysis early in the design phase and continuously throughout the development of the product. These risks are controlled via measures realized during software development, testing and product labeling.

Furthermore, the device is intended for healthcare professionals familiar with the post processing of CT images.

13. Substantial Equivalence and Conclusion

AI-Rad Companion (Pulmonary) is substantially equivalent to the follow predicate device (**Table 5**):

Predicate Device	FDA Clearance Number	FDA Clearance Date	Main Product Code
AI-Rad Companion (Pulmonary)	K213713	August 11, 2022	JAK

Table 5: Predicate device for AI-Rad Companion (Pulmonary)

AI-Rad Companion (Pulmonary) has the same intended use and similar technical characteristics compared to the predicate device, AI-Rad Companion (Pulmonary) [K213713], with respect to the software features, functionalities and core algorithms. The enhancements and improvements provided in AI-Rad Companion (Pulmonary) increase the clinical utility and reduce the complexity of the imaging workflow for the clinical user. The conclusions from all verification and validation data suggest that these enhancements are equivalent with respect to safety and effectiveness of the predicate device. These modifications do not change the intended use of the product.