August 11, 2022

Siemens Healthcare GmBh
% Kira Kuzmenchuk
Regulatory Affairs Specialist
40 Liberty Blvd. Mail Code 65-1A
MALVERN PA 19355

Re: K213713
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: July 15, 2022
Received: July 18, 2022

Dear Kira Kuzmenchuk:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Laurel Burk, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213713

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 emergency medicine, specialty care, urgent 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 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.

510(k) SUMMARY
FOR
AI-RAD COMPANION (Pulmonary)
SW version VA20

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: November 23, 2021

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

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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:	K183271
Clearance Date:	July 26, 2019
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:	LLZ
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 emergency medicine, specialty care, urgent 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 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.

6. Device Description

AI-Rad Companion (Pulmonary) SW version VA20 is an enhancement to the previously cleared device AI-Rad Companion (Pulmonary) K183271 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:

- Modified Indications for Use Statement
  The indications for use statement was updated to include descriptive text for the lung lesion follow feature.

- Updated Subject Device Claims List
  The claims list was updated to include claim pertaining to the lung lesion follow up feature.

- Lung Lesion Follow-up Assessment of current and prior lesions
  This feature provides the possibility to compare currently segmented lung lesions with corresponding priors and changes to the correlated data are assessed quantitatively.

- Pulmonary Density Assessment
  This feature provides the possibility to segment opacity regions inside the lung using an AI algorithm. AI-Rad Companion (Pulmonary) counts image voxels inside opacity regions and calculates the percentages of these voxels relative to the total number of voxels per lobe, lung and in total. Afterwards, each of the five lung lobes is assigned a score ranging from 0 to 4 based on the percentage of opacity as follows: 0 (0%), 1 (1%–25%), 2 (26%–50%), 3 (51%–75%), or 4 (76%–100%). Then a summation of the five lobe scores (range of possible scores, 0–20) are generated in the device outputs. This functionality is commercially available on the Siemens syngo.CT Extended Functionality (K203699).

- Bi-Directional Lesion Diameter
  This feature provides an additional measurement derived from the existing segmentation contour of a lung lesion. The existing list of measurements is extended with the maximum orthogonal diameter in 2D (short axis diameter) which is orthogonal to the lesion's maximum 2D diameter (2D diameter, long axis diameter). This functionality is commercially available on the Siemens syngo.CT Extended Functionality (K203699).

- Architecture Enhancement for on premise Edge deployment
  The system supports the existing cloud deployment as well as an on premise "edge" deployment. The system remains hosted in the teamplay digital health platform and remains driven by the AI-Rad Companion Engine. Now the edge deployment implies that the processing of clinical data and the generation of results can be performed on-premises within the customer network. The edge system is fully connected to the cloud for monitoring and maintenance of the system from remote.

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) VA20	Predicate Device AI-Rad Companion (Pulmonary) (K183271)
Modality	CT	CT
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.
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.
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.
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.
Pulmonary Density	AI-based identification of areas with elevated Hounsfield values. Threshold-based identification of highest elevated Hounsfield values	N/A

	inside these elevated regions, by a predefined threshold of -200 HU	
Visualization of segmentation and parenchyma results	Color overlay of MPR and VRT with evaluation results	Color overlay of MPR and VRT with evaluation results
Interface to LungCAD	Interface to syngo.CT LungCAD	Interface to syngo.CT LungCAD
Lesion segmentation	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 [%])	Segmentation of lung lesions with the following data (not shown to the user): • 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 [%])
Visualization of lesion segmentation results	Color overlay of MPR and VRT with evaluation	Color overlay of MPR and VRT with evaluation
Lesion follow-up	Correlation of segmented lung lesions with known priors using the data from the lesion segmentation.	N/A
Deployment	Cloud and Edge (on-premise) deployments	Cloud deployment

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 Software Contained in Medical Devices" (May 11, 2005) 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
5-114	General	Medical Devices – Application of usability engineering to medical devices [including Corrigendum 1 (2016)]	62366-1: 2015-02	IEC
5-125	General	Medical Devices – application of risk management to medical devices	14971:2019	ISO
13-79	Software/ Informatics	Medical device software – software life cycle processes [Including Amendment 1 (2016)]	62304: 2006/A1:2016	AAMI ANSI IEC
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 (2016)	NEMA
12-261	Radiology	Information Technology – Digital Compression and coding of continuous -tone still images: Requirements and Guidelines [including: Technical Corrigendum 1(2005)]	10918-1 1994-02-15	ISO IEC

Table 2: Voluntary Conformance Standards

Verification and Validation

Software documentation for a Moderate Level of Concern software, per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, is also included as part of this submission. Non-clinical tests were conducted on the subject device during product development.

Non-clinical tests (unit, integration and system) were conducted on AI-Rad Companion (Pulmonary) during product development. Additionally, the lesion follow-up feature was validated with a non-clinical bench test to assess the identification of lesion pairs. In an evaluation of 200 cases to identify lesion pairs, the algorithm had a sensitivity of 94.3% and an average PPV of 99.1% across all subgroups.

Siemens Healthineers adheres to the cybersecurity requirements as defined the FDA Guidance "Content of Premarket Submission for Management of Cybersecurity in Medical Devices:

Guidance for Industry and Food and Drug Administration Staff" (October 18, 2018) 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. Clinical Tests

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.

10. 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 magnetic resonance images.

11. Substantial Equivalence and Conclusion

AI-Rad Companion (Pulmonary) is substantially equivalent to the follow predicate device (**Table 2**):

Predicate Device	FDA Clearance Number	FDA Clearance Date	Main Product Code
AI-Rad Companion (Pulmonary)	K183271	July 26, 2019	JAK

Table 2: Predicate device for AI-Rad Companion (Pulmonary)

AI-Rad Companion (Pulmonary) has the same intended use and technical characteristics compared to the predicate device, AI-Rad Companion (Pulmonary) [K183271], 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. Siemens is of the opinion that AI-Rad Companion (Pulmonary) is substantially equivalent to the currently marketed predicate device.