December 6, 2021

Siemens Medical Solutions USA, Inc.
% Alaine Medio
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE TN 37932

Re: K213096
Trade/Device Name: Al-Rad Companion (Pulmonary)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: September 23, 2021
Received: September 24, 2021

Dear Alaine Medio:

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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213096

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 found lung lesions and dedication to corresponding lung lobe.
- 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

Prepared December 01, 2021

I. Identification of the Submitter

Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number
2240869

Manufacturing Site
Siemens Healthcare GmbH
Siemensstr 1
D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Submitter Contact Person:
Alaine Medio
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
810 Innovation Drive
Knoxville, TN 37932
Phone: (865) 206-0337
Fax: (865) 218-3019
Email: alaine.medio@siemens-healthineers.com

Secondary Contact Person:
Tabitha Estes
Regulatory Affairs Specialist
Phone: (865) 804-4553
Email: Tabitha.estes@siemens-healthineers.com

II. Device Name and Classification

Product Name:	AI-Rad Companion (Pulmonary)
Propriety Trade Name:	AI-Rad Companion (Pulmonary)
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology

CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

III. Predicate Device

Primary Predicate Device:

Trade Name:	AI-Rad Companion (Pulmonary)
510(k) Number:	K183271
Clearance Date:	07/26/2019
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK, LLZ

Secondary Predicate Device:

Trade Name:	syngo.CT Extended Functionality
510(k) Number:	K203699
Clearance Date:	04/30/2021
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

IV. Device Description

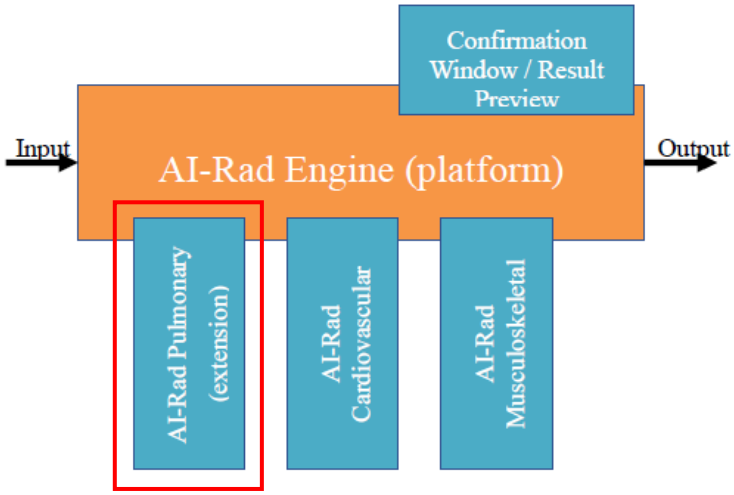
Al-Rad Companion is a software only medical system that investigates data from imaging systems. Al-Rad Companion receives these data and checks which post-processing algorithms may be applicable. Data that does not meet the Al-Rad Companion requirements are ignored while data that meets the requirements are sent for further processing. Applicable data are processed, and the results are provided to the user via their clinical workplace. The user has the option to accept, review or withdraw single results of Al-Rad Companion.

Al-Rad Companion includes a software operating platform (Al-Rad Companion (Engine)) and optional clinical extensions such as Al-Rad Companion (Pulmonary), Al-Rad Companion (Musculoskeletal) and Al-Rad Companion (Cardiovascular). The clinical extensions are post-processing applications that operate on the Al-Rad Companion (Engine) software platform and process CT datasets in specific regions of the thorax or use datasets from other modalities. The basic post-processing functions are landmark detection, segmentation, and classification. Al-Rad Companion uses Artificial Intelligence (AI)-algorithms.

The AI-Rad Companion (Engine) platform is the interface for incoming and outgoing data for the complete AI-Rad Companion system that provides input data and collects results and status information

from the extensions. Additionally, it is the interface for incoming and outgoing data for the complete AI-Rad Companion system.

The AI-Rad Companion extensions are optional post-processing applications that operate on the AI-Rad Companion (Engine) software platform. The platform and each of the extensions are distinct software components and thus separate medical devices. A pictorial representation of the interaction between the AI-Rad Companion (Engine) and optional AI-Rad Companion extensions is provided in the figure below.



The scope of this submission is the extension AI-Rad Companion (Pulmonary). It is an image post-processing software that uses CT DICOM data to support clinicians in the evaluation and assessment of lung diseases. It 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. The major functionalities of AI-Rad Companion (Pulmonary) are as follows:

- Segmentation and measurements of complete lung, lungs, and lung lobes.
- Identification of areas with lower Hounsfield values in comparison to a predefined threshold for complete lung and lung lobes.
- Segmentation and measurements of found lung lesions
- Identification of areas with elevated Hounsfield values, where areas with elevated versus high opacities are distinguished

The results will be delivered in different image formats and, depending on the configuration, can be verified in the Results Preview and will be included in the overview with all findings. This will include DICOM Structured Report with measurements results

The software version VA13 of the AI-Rad Companion (Pulmonary) includes the following modifications:

- **Pulmonary Density**
  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, the opacity results are assigned to a certain range as defined by Bernheim et al.

  This feature has been cleared with the secondary predicate device syngo.CT Extended Functionality VB51 (K203699, clearance date 04/30/2021). It is a reuse from the predicate device to this subject device. The feature and its algorithms remain unchanged from this predicate device.

- **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 feature has been cleared with the secondary predicate device syngo.CT Extended Functionality VB51 (K203699). It is a reuse from the predicate device to this subject device. For this feature, no modifications are required to the detection nor the segmentation of the lung lesions.

- **Cloud and Edge Deployment**
  The system supports the existing cloud deployment as well as a new 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 allows the processing of clinical data and the generation of results on-premises within the customer network. The edge system is fully connected to the cloud for monitoring and maintenance of the system from remote.

V. 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 found lung lesions and dedication to corresponding lung lobe
- 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.

VI. Comparison of Technological Characteristics with the Predicate Device

The comparison between the above referenced predicate devices is listed in the following table. It compares each feature of the subject device either with the primary predicate device or the secondary predicate device.

Subject Device	**Primary Predicate Device**	**Secondary Predicate Device**	**Comparison**
AI-Rad Companion (Pulmonary) VA13A (K213096)	AI-Rad Companion (Pulmonary) VA10A (K183271)	syngo.CT Extended Functionality VB51 (K203699)	
Segmentation of Lung			
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.	Creation of a lung segmentation mask by combining the segmentation masks of 5 lung lobes.	*The same algorithm as cleared with the predicate devices is used.* *Additional training data was added as compared to the primary predicate for the Pulmonary Density Feature. This same data and method were used with the secondary predicate device (K203699).*
Segmentation of 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.	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.	
Opacity Detection			
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.	N/A	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.	*The Opacity Detection is the same as the secondary predicate devices syngo.CT Extended Functionality (K203699).*
Measurement Results			
Lung lesion, lung parenchyma, and pulmonary density measurements.	Lung lesion, and lung parenchyma measurements.	Pulmonary density measurements.	*Extended with Pulmonary Density results, as cleared in the secondary predicate device (syngo.CT Extended Functionality (K203699).*
Parenchyma Evaluation			

Subject Device	Primary Predicate Device	Secondary Predicate Device	Comparison
AI-Rad Companion (Pulmonary) VA13A (K213096)	AI-Rad Companion (Pulmonary) VA10A (K183271)	syngo.CT Extended Functionality VB51 (K203699)	
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.	N/A	*Same as the primary predicate device AI-Rad Companion (Pulmonary) VA10A (K183271).*
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.	N/A	
Visualization of Segmentation and Parenchyma Results			
Color overlay of MPR and VRT with evaluation results.	Color overlay of MPR and VRT with evaluation results.	N/A	
LungCAD Interface			
The external device syngo.CT LungCAD is connected.	The external device syngo.CT LungCAD is connected.	The external device syngo.CT LungCAD is connected.	*Same as both predicate devices.*
Based on the positions provided via the LungCAD Interface, a segmentation of suspicious lung areas is started. Within the derived contours the maximum diameter within one slice, the 3-dimensional diameter, and the volume are determined. The lesion is dedicated to a lung lobe. Additionally, the maximum orthogonal 2D diameter is measured and the mean from maximum 2D diameter and maximum orthogonal 2D diameter is shown.	Based on the positions provided via the LungCAD Interface, a segmentation of suspicious lung areas is started. Within the derived contours the maximum diameter within one slice, the 3-dimensional diameter, and the volume are determined. The lesion is dedicated to a lung lobe.	Based on positions provided by the user, a segmentation of suspicious lung areas is started. Within the derived contours the maximum diameter within one slice, the 3-dimensional diameter, and the volume are determined. The lesion is dedicated to a lung lobe. Additionally, the maximum orthogonal 2D diameter is measured and the mean from maximum 2D diameter and maximum orthogonal 2D diameter is shown.	*The Bi-directional lesion diameter is the same as the secondary predicate device syngo.CT Extended Functionality VB51 (K203699).*

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing

Non-clinical tests (integration and functional) were conducted for AI-Rad Companion (Pulmonary) during product development. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

Clinical Evaluation of the AI-based Algorithms

The following activities have been conducted for the syngo.CT Extended Functionality VB51 software application, to evaluate the feature Pulmonary Density which has been introduced with this application. The K-number is K203699 and it has been considered as the secondary predicate device for this submission K213096:

Clinical Data Based Software Validation

The following algorithms underwent a scientific evaluation:

- Segmentation of lung lobes
  The lung lobe segmentation algorithm computes 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.
- Identification of opaque regions (AI-based)
  The algorithm computes masks of opaque regions in the lung for a given CT data set of the chest. The opaque regions include ground glass opacities, consolidations and crazy-paving patterns. The calculation is done for each lobe as well as for the complete lung.

For each algorithm of Pulmonary Density the analysis is structured as follows:

- Algorithm Description: purpose, functionality, technical description
- Data
  - Training cohort: size and properties of data used for training
  - Description of ground truth / annotations generation
  - Validation cohort: size and properties of data used for testing/validation
- Performance
  - Choice of performance metric
  - Actual performance results
  - Assessment of clinical relevance of achieved performance
- Related clinical research, e.g. publications (if applicable)

The results of clinical data-based software validation for the feature Pulmonary Density demonstrated equivalent performance in comparison to the primary predicate device for segmentation and lung parenchyma categorization.

Performance of lung lobe segmentation of AI-Rad Companion (Pulmonary) device has been validated using 250 datasets from multiple sites across the US and Europe. Average DICE coefficients ranged from 0.94 to 0.96.

Performance of the segmentation of opaque regions of AI-Rad Companion Pulmonary device has been validated using 150 datasets from multiple sites across the US and Europe. Interreader-variability of the percentage of opacity (PO) was assessed on a lung lobe level and 95%-Limits of Agreement (LoA) were established. The algorithm performance was compared against the human reads and 93.0% of the PO values were found within the LoA.

Additional analysis was performed for both population-specific subgroups and various technical parameters and consistent performance has been found for both algorithms across all subgroups.

Risk Analysis

The risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results demonstrate that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Siemens hereby certifies that AI-Rad Companion (Pulmonary) meets the following voluntary standards covering electrical and mechanical safety listed below:

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)	01/14/2019	AAMI, ANSI, IEC
5-125	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Third Edition 2019-12	12/23/2019	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	12/23/2016	IEC

VIII. Conclusion

AI-Rad Companion (Pulmonary) has the same intended use and similar indication for use as the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The comparison of technological characteristics, non-clinical performance data, and software validation demonstrates that the subject device is as safe and as the predicate device that is currently marketed for the same intended use.

For the subject device, AI-Rad Companion (Pulmonary) VA13, Siemens used the same testing with the same workflows as used to clear the predicate device in addition to the clinical evaluation. Siemens considers AI-Rad Companion (Pulmonary) version VA13 to be as safe, as effective and with performance substantially equivalent to the commercially available predicate device.