Siemens Medical Solutions USA, Inc.
Kimberly Rendon
40 Liberty Blvd.
MALVERN, PA 19355

July 26, 2019

Re: K183271
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, LLZ
Dated: June 14, 2019
Received: June 17, 2019

Dear Kimberly Rendon:

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 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)*
K183271

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY
AI-RAD COMPANION (PULMONARY)
K183271

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard Malvern, PA 19355
Date Prepared: July 19, 2019

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

I. Submitter

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

Manufacturing Site
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Henkestrasse 127
91052 Erlangen, Germany
Establishment Registration Number
3004977335

Contact Person
Kimberly Rendon
Sr. Manager Regulatory Affairs
(610) 448-6480
kimberly.rendon@siemens-healthineers.com

II. Device Name and Classification

Product Name:	AI-Rad Companion (Pulmonary)
Trade Name:	AI-Rad Companion (Pulmonary)
Classification Name:	Computed Tomography X-ray System
Secondary Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Secondary Product Code:	LLZ

III. Predicate Device

Primary Predicate Device:

Product Name:	syngo.CT Pulmo 3D
Propriety Trade Name:	syngo.CT Pulmo 3D
510(k) Number:	K123540
Clearance Date:	August 29, 2013
Classification Name:	Computed Tomography X-Ray System
Secondary Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750

Device Class:	Class II
Primary Product Code:	JAK
Secondary Product Code:	LLZ

Recall Information: There are currently no recalls for this device

Secondary Predicate Device:

Product Name:	syngo.PET&CT Oncology
Propriety Trade Name:	syngo.PET&CT Oncology
510(k) Number:	K093621
Clearance Date:	February 23, 2010
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Primary Product Code:	LLZ
Recall Information:	There are currently no recalls for this device

IV. Device Description

This section described the technical features and workflow for subject device AI-Rad Companion (Pulmonary). AI-Rad Companion (Pulmonary) is a software only image processing application that supports quantitative and qualitative analysis of previously acquired CT DICOM Images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation of and assessment of disease of the thorax.

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

1) Modified Indication for Use Statement
2) Software version VA10A, including the following features:
    a) Segmentation of the lung (**modified**)
    b) Segmentation of lung lobes based on deep learning algorithm (**modified**)
    c) Parenchyma evaluation (**modified**)
    d) Lesion segmentation (**modified**)
3) Subject device claims list

The subject device AI-Rad Companion (Pulmonary) is an image processing software that provides 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 subject device supports the following device specific functionality:

- Segmentation and volume 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
- Detection of solid pulmonary nodules with the assistance of LungCAD (K143196, clearance date 05/12/2015) and dedication to lung lobe
- Segmentation and measurements of identified lung lesions

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.

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

In comparison the predicate device, the subject devices provide comparable outputs in terms of lung and lung lobe visualization/segmentation and lung lesion segmentation and labeling. A tabular comparison of the subject device and predicate devices is provided as Table 1 below.

Table 1: Predicate Device Comparable Properties

Feature	Subject Device	Predicate Device	Comparison Results
	Siemens AI-Rad Companion (Pulmonary)	**Siemens syngo.CT Pulmo 3D (K123540, clearance date 8/29/2013)**	
Segmentation of lungs	Segmentation of lungs	Segmentation of left / right lung	***Modified*** **subject device:** segmentation of complete lungs **predicate device:** dedicated algorithm for segmentation of both lungs
Segmentation of lung lobes	Segmentation of lung lobes	Segmentation of lung thirds, lung core/peel, lung lobes	***Modified*** **subject device:** deep learning-based algorithm for long lobes segmentation **predicate device:** Model-based segmentation algorithm
Parenchyma Evaluation	Calculation and visualization of lung tissue below -950 HU	Calculation and visualization of lung tissue below threshold	***Modified*** **Subject device:** fixed threshold for segmentation **Predicate device**: Configurable threshold for segmentation

Feature	Subject Device	Predicate Device	Comparison Results
	Siemens AI-Rad Companion (Pulmonary)	**Siemens syngo.CT Pulmo 3D (K123540, clearance date 8/29/2013)**	
Visualization of segmentation and parenchyma results	Color overlay of MPR and VRT with evaluation results	Color overlay of MPR and VRT with evaluation results	***Same***
Feature	**Siemens AI-Rad Companion (Pulmonary)**	**Siemens syngo.PET&CT Oncology (K093621, clearance date 02/23/2010)**	**Comparison Results**
Interface to LungCAD	Interface to syngo.CT LungCAD (K143196) is supported	Interface to syngo.CT LungCAD (K143196) is supported	***Same***
Lesion Segmentation	Segmentation of lung lesions	Segmentation of lesions of the lung, liver, and lymph nodes	***Modified*** **subject device:** segmentation of lung lesions and localization of found lesion to lung lobe **predicate device:** segmentation of lesions of lung, liver, lymph nodes, and general anatomies
Visualization of lesion segmentation results	Color overlay of MPR and VRT with evaluation results	Color overlay of MPR and VRT with evaluation results	***Same***

The subject device modifications referenced above do not raise different questions of safety or effectiveness in comparison to the predicate devices.

VII. Performance Data

Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of AI-Rad Companion (Pulmonary). Software validations, bench testing, and clinical data-based software validations have been conducted to the performance claims as well as the claim of substantial equivalence to the predicate devices. AI-Rad Companion has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrated that AI-Rad Companion complies with the following voluntary FDA recognized Consensus Standards listed in Table 2 on the next page:

Table 2: Voluntary Conformance Standards

Recognition Number	Product Area	Title of Standard	Publication Date	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-32	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)	08/20/2012	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	08/20/2012	ISO
5-95	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	06/27/2016	IEC

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, and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the Subject Device AI-Rad Companion (Pulmonary) software version VA10 during product development.

The Risk 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. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Bench testing in the form of Unit, Subsystem and System Integration testing were performed to evaluate the performance and functionality of the new features and software updates. All testable requirements in the Engineering Requirements Specifications keys, Subsystem Requirements Specifications keys, and the Risk Management Hazard keys have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process. The software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans. Electrical safety and EMC testing requirements are addressed as part of the host system (CT device or PACS system) to ensure compliance with the application IEC standards.

Siemens conforms to the cybersecurity requirements 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. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital.

Clinical Data Based Software Validation

To validate the AI-Rad Companion (Pulmonary) clinical workflow, 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 lobe (LLL) for a given CT data set of the chest.

- **Evaluation of the lung parenchyma**

The algorithm receives a 3D CT data set and binary masks of the segmented lung lobes. It computes, the ratio of voxels below -950 HU (%LAV950) each lobe as well as for the complete lung.

For each algorithm of AI-Rad Companion 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 subject device AI-Rad Companion (Pulmonary) demonstrated superior performance in comparison to the primary predicate device for segmentation. A complete scientific evaluation report is provided in support of the device modifications.

Performance of lung lobe segmentation of AI-Rad Companion.Pulmonary device has been validated in a retrospective performance study (n>4,500 CT data sets from multiple clinical sites from within and outside United States). In this study DICE coefficients, surface metrics and volume error have been computed by comparing the output of the algorithm to the manually established ground truth. The average DICE coefficients for the individual lung lobes ranged between 0.95 and 0.98 with a standard deviation (SD) <= 0.07. Mean surface distance ranged between 0.5 and 1.0 mm with SD <=1.5 mm. The 95th quantile of the Hausdorff distance ranged between 2.6 and 5.2 mm with SD <=6.7 mm. Volume error was between 1.5 and 3.5 % with SD <= 7.3 %.

All performance results were superior to the ones achieved using the predicate device supporting substantial equivalence.

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

Summary
AI-Rad Companion (Pulmonary) was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process and clinical data-based software validation. The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual and in clinical use tests with customer report and feedback form. Customer employees are adequately trained in the use of this equipment.

VIII. General Safety and Effectiveness Concerns:
The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a system related Risk analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. In order to minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

IX. Conclusion
AI-Rad Companion (Pulmonary) has the same intended use as the primary predicate device. The indication for use has been modified to include a more succinct summary of device specific performance but is still within the scope of the general intended use and regulatory classification as the predicate devices. The

fundamental technological characteristics such as image visualization and image manipulation are the same as the predicate devices. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The predicate devices were cleared based on non-clinical supportive information including bench testing and software validations. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The comparison of technological characteristics, non-clinical performance data, and software validation demonstrates that the subject device is as safe and effective when compared to the predicate device that is currently marketed for the same intended use. For the subject device, AI-Rad Companion (Pulmonary), Siemens used the same testing with the same workflows as used to clear the predicate device to demonstrate safety and performance of the technical workflow. Clinical applicability was demonstrated via software-data based validations that were derived in the same intended environment as the predicate devices. Since both devices were tested using the same methods, Siemens believes that the data generated from the AI-Rad Companion (Pulmonary) software testing supports a finding of substantial equivalence.