September 10, 2019

Siemens Medical Solutions USA, Inc.
% Mrs. Kimberly Rendon
Senior Manager, Regulatory Affairs
40 Liberty Blvd., Mail Code: 65-1A
MALVERN PA 19355

Re: K183268
Trade/Device Name: AI-Rad Companion (Cardiovascular)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray System
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: August 15, 2019
Received: August 19, 2019

Dear Mrs. 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,

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)*
K183268

Device Name
AI-Rad Companion (Cardiovascular)

Indications for Use *(Describe)*
AI-Rad Companion (Cardiovascular) 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 cardiovascular diseases.

It provides the following functionality:
• Segmentation and volume measurement of the heart
• Quantification of the total calcium volume in the coronary arteries
• Segmentation of the aorta
• Measurement of maximum diameters of the aorta at typical landmarks
• Threshold-based highlighting of enlarged diameters

The software has been validated for non-cardiac chest CT data with filtered backprojection reconstruction from Siemens Healthineers, GE Healthcare, Philips, and Toshiba/Canon. Additionally, the calcium detection feature has been validated on non-cardiac chest CT data with iterative reconstruction from Siemens Healthineers.

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
AI-RAD COMPANION (CARDIOVASCULAR)
K183268

Date Prepared: August 14, 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
Siemens Healthcare GmbH
Siemensstrasse 1 D-91301
Forchheim, Germany
Establishment Registration Number
3004977335

Contact Person
Kimberly Rendon
Sr. Manager, Regulatory Affairs

II. Device Name and Classification

Product/Proprietary Trade Name:	AI-Rad Companion (Cardiovascular)
Classification Name:	Computed Tomography X-ray 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/Proprietary Trade Name:	syngo.CT Calcium Scoring
510(k) Number:	K990426
Clearance Date:	05/12/1999
Classification Name:	Computed Tomography X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Primary Product Code:	JAK
Recall Information:	There are currently no recalls for this device

Secondary Predicate Device:

Product/Proprietary Trade Name:	syngo.CT Cardiac Function
510(k) Number:	K123585
Clearance Date:	12/20/2012
Classification Name:	Computed Tomography X-Ray System
Classification Panel:	Radiology

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CFR Section:	21 CFR §892.1750
Device Class:	Class II
Primary Product Code:	JAK
Recall Information:	There are currently no recalls for this device

Secondary Predicate Device:

Product/Proprietary Trade Name:	syngo aortic Valve Guide
510(k) Number:	K113027
Clearance Date:	11/22/2011
Classification Name:	Interventional Fluoroscopic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650
Device Class:	Class II
Primary Product Code:	OWB
Secondary Product Code:	JAA

IV. Device Description

In general, AI-Rad Companion (Cardiovascular) is a software only image post-processing application that uses deep learning algorithms to post-process CT data of the thorax. As an update to the previously cleared devices, the following modifications have been made:

1) Modified Indication for Use Statement
2) Support of software AI-Rad Companion CT VA10A
   a) Heart segmentation including measurements (**modified**)
   b) Calcium detection based on deep learning algorithm (**modified**)
   c) Aorta segmentation (**modified**)
   d) AHA landmarks for labeling and diameter measurement of the aorta, including threshold-based aorta diameter classification (**modified**)
3) Subject device claims list

The subject device AI-Rad Companion (Cardiovascular) is an image processing software that utilizes deep learning algorithms to provide 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 thorax. The subject device supports the following device specific functionality:

- Segmentation and volume measurement of heart
- Identification and measurement of volume with high Hounsfield values –-related to coronary calcification
- Segmentation of the aorta and determination of 9 Landmarks
- Computation of cross-sectional MPRs at the 9 landmarks and their maximum diameter
- Measurement of maximum diameters of the aorta at typical landmarks
- Threshold-based classification of diameters into different categories

V. Indications for Use

AI-Rad Companion (Cardiovascular) 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 cardiovascular diseases.

It provides the following functionality:

- Segmentation and volume measurement of the heart
- Quantification of the total calcium volume in the coronary arteries
- Segmentation of the aorta

- Measurement of maximum diameters of the aorta at typical landmarks
- Threshold-based highlighting of enlarged diameters

The software has been validated for non-cardiac chest CT data with filtered backprojection reconstruction from Siemens Healthineers, GE Healthcare, Philips, and Toshiba/Canon. Additionally, the calcium detection feature has been validated on non-cardiac chest CT data with iterative reconstruction from Siemens Healthineers.

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 heart/aorta segmentation, coronary calcium visualization and grading, heart/aorta measurement, and labeling. A tabular comparison of the subject device and predicate devices is provided as Table 1 below.

Table 1: Predicate Device Comparable Properties

Subject Device	**Predicate Device**	**Comparison Results**
Siemens AI-Rad Companion (Cardiovascular)	**Siemens syngo.CT Cardiac Function *(K123585)***	
AI-based Heart Segmentation	Model-based Heart Isolation	***Modified*** **subject device:** deep learning-based algorithm **predicate device:** model-based segmentation algorithm
Color overlay of MPR and VRT with evaluation results	Basic Reading Functionality	***Same***
Siemens AI-Rad Companion (Cardiovascular)	**Siemens syngo CaScoring *(K990426)***	**Comparison Results**
Calcium Detection	Automatic detection of coronary vessels and coronary calcium	***Modified*** **subject device:** deep learning-based algorithm **predicate device:** model-based segmentation algorithm
Siemens AI-Rad Companion (Cardiovascular)	**Siemens ValveGuide (K113027)**	**Comparison Results**
Aorta Segmentation	Aortic root segmentation	***Modified*** **subject device:** deep learning-based algorithm **predicate device:** model-based segmentation algorithm
Landmark Detection	Landmark detection	**Modified** **subject device:** deep learning-based algorithm, 9 AHA positions **predicate device:** model-based segmentation algorithm, aortic root plane
Aorta diameter measurements	Aorta diameter measurements	**Same**
Aorta categories	N/A	***New*** measurements are compared with results from a standard population, deviations are signalized to the user
Color overlay of MPR and VRT with evaluation results	Basic Reading Functionality	**Same**

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VII. Performance Data

Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of AI-Rad Companion (Cardiovascular). 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 below.

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

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 (Cardiovascular) 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 (Cardiovascular) software from clinical perspective, the following algorithms underwent a scientific evaluation:

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- **Segmentation of heart**
  The heart segmentation algorithm computes a segmentation mask of the heart for a given non-cardiac chest CT data set. The output segmentation mask is then used to compute of the heart volume and to define a region of interest for the coronary calcium detection algorithm.
- **Detection of coronary calcium**
  The algorithm detects calcifications in the coronary arteries for a given non-cardiac chest CT data set (without contrast, maximum slice thickness is 3 mm). The output is the total volume of the detected coronary calcium.
- **Segmentation of aorta**
  The algorithm computes segmentation masks of the aorta for a given non-cardiac chest CT data set.
- **Detection of aortic landmarks**
  Detection of anatomical landmarks (salient 3D points) is used to find out if and where a particular structure is located within the 3D image data. In particular the aortic landmarks are used to identify locations for diameter measurements.
- **Aorta diameter measurements**
  Based on a segmented mask of the aorta and a series of detected aortic landmarks, the algorithm computes aortic landmarks according to guidelines of the American Heart Association (AHA)[1] provides the corresponding maximum aortic diameters.
- **Threshold-based categorization of diameter measurements**
  The algorithm receives maximum aortic diameters at AHA-locations and applies the thresholds given in the AHA standard. The results are then labelled accordingly.

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 (Cardiovascular) demonstrated equivalent performance in comparison to the primary predicate device. A complete scientific evaluation report is provided in support of the device modifications.

The performance of the AI-Rad Companion (Cardiovascular) device has been validated in retrospective performance studies on non-cardiac chest CT data from multiple clinical sites across the United States. With respect to the cardiac function, logarithmic correlation coefficient of total coronary calcium volume between subject and predicate device was 0.96 (N=381). With respect to the aorta function the average absolute error in aorta diameters was 1.6 mm (95% confidence interval: [1.5 mm, 1.7 mm]) across all nine measurement locations and varied between 0.9 mm and 2.4 mm per location (N=193). Performance was consistent for all critical subgroups, such as vendors or slice thickness.

Summary
AI-Rad Companion (Cardiovascular) 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

[1] LF Hiratzka, GL Bakris, JA Beckman, et al., "2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM guidelines for the diagnosis and management of patients with thoracic aortic disease", Circulation. 2010; 121:e266-e369

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. Conclusions

AI-Rad Companion (Cardiovascular) has the same intended use as the predicate devices. 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 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 device. 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 (Cardiovascular), 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 (Cardiovascular) software testing supports a finding of substantial equivalence