Siemens Medical Solutions USA, Inc.
c/o Tabitha Estes
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE, TN 37932

December 17, 2019

Re: K192763
Trade/Device Name: syngo.CT CaScoring
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 27, 2019
Received: September 30, 2019

Dear Tabitha Estes:

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)*

K192763

Device Name
syngo.CT CaScoring

Indications for Use *(Describe)*
syngo.CT CaScoring is an image analysis software package for evaluating CT data sets.

The software is designed to support the physician in evaluating and documenting calcified coronary lesions, using standard or low-dose spiral or sequential CT scanning data sets. After loading noncontrasted cardiac CT images, syngo.CT CaScoring can be used to interactively mark calcified coronary lesions and to allocate each lesion to one of several coronary arteries, that is, the right coronary artery (RCA), the left main coronary artery (LM), the left anterior descending artery (LAD), and the left circumflex artery (CX).

syngo.CT CaScoring calculates the Agatston equivalent score, the mass score and the volume score of each coronary artery as well as the corresponding total scores across all coronary arteries. syngo.CT CaScoring allows the user to create a paper report including the calcium scoring data, any user-documented images, cited literature and additional relevant information.

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
FOR
SYNGO.CT CASCORING

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

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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II. Device Name and Classification

Product Name:	syngo.CT CaScoring
Propriety Trade Name:	syngo.CT CaScoring
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

III. Predicate Device

Primary Predicate Device:

Trade Name:	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
Product Code:	90JAK
Recall Information:	There are currently no recalls for this device.

Secondary Predicate Device:

Trade Name:	HealthCCS
510(k) Number:	K172983
Clearance Date:	06/13/2018
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	90JAK

IV. Device Description

syngo.CT CaScoring is a post processing application designed to support the physician in evaluating and documenting calcified coronary lesions. After loading non-contrasted cardiac CT images, syngo.CT CaScoring can be used to interactively mark calcified coronary lesions and to allocate each lesion to one of several coronary arteries, that is, the right coronary artery (RCA), the left main coronary artery (LM), the left anterior descending artery (LAD), and the left circumflex artery (CX). syngo.CT CaScoring calculates the Agatston equivalent score, the mass score and the volume score of each coronary artery as well as the corresponding total scores across all coronary arteries. syngo.CT CaScoring allows the user to create a paper report including the calcium scoring data, any user-documented images, cited literature and additional relevant information.

A listing of device modifications as part of the new software version SOMARIS/8 VB40 of syngo.CT CaScoring is as follows:

- Updated Indications for Use Statement
- Support of the CaScoring algorithm to precompute the calcium score
- Support of Rapid Results Technology for the CaScoring algorithm

V. Indications for Use

syngo.CT CaScoring is an image analysis software package for evaluating CT data sets.

The software is designed to support the physician in evaluating and documenting calcified coronary lesions, using standard or low-dose spiral or sequential CT scanning data sets. After loading noncontrasted cardiac CT images, syngo.CT CaScoring can be used to interactively mark calcified coronary lesions and to allocate each lesion to one of several coronary arteries, that is, the right coronary artery (RCA), the left main coronary artery (LM), the left anterior descending artery (LAD), and the left circumflex artery (CX).

syngo.CT CaScoring calculates the Agatston equivalent score, the mass score and the volume score of each coronary artery as well as the corresponding total scores across all coronary arteries. syngo.CT CaScoring allows the user to create a paper report including the calcium scoring data, any user-documented images, cited literature and additional relevant information.

VI. Comparison of Technological Characteristics with the Predicate Device

syngo.CT CaScoring is a post-processing application operating on the multi-user syngo.via client/server platform. It provides the same fundamental technology as the primary predicate device Calcium Scoring

(e. g. evaluation and documentation of calcified coronary lesions, calculation of the Agatston equivalent score). The automated calcium scoring algorithm which is implemented in the software version SOMARIS/8 VB40 of the subject device is equivalent to the secondary predicate device HealthCCS. The automatic calcium scoring algorithm works in the same manner as cleared with the secondary predicate device. From a functional perspective there are no differences. The difference between the subject device and the secondary predicate device is, syngo.CT CaScoring can send DICOM data to any generic DICOM viewer. This information flow has been realized for other Siemens post-processing applications (e.g. syngo.CT Single Source Dual Energy (Twin Beam), K163289, clearance date 02/09/2017).

The differences between the above referenced predicate devices are described at a high-level in the table below:

Feature	**Subject Device**	**Predicate Devices**
	syngo.CT CaScoring	Calcium Scoring *K990426*
		HealthCCS *K172983*
Automated Calcium Scoring Evaluation	Assignment of a probability of a candidate being a coronary calcification based on location within the heart, density, shape and similar properties: if the probability of a candidate is higher than a predefined threshold, the candidate is labelled as a calcification. In addition, results of the evaluation can be sent via Rapid Results Technology any generic DICOM viewer.	The technology is equivalent to HealthCCS: Assignment of a probability of a candidate being a coronary calcification based on location within the heart, density, shape and similar properties: if the probability of a candidate is higher than a predefined threshold, the candidate is labelled as a calcification.
Browsing, selecting, and displaying images for searching calcium regions/lesions	Yes	Yes
Interactive definition of ROIs and assignment of the four major coronary arteries (LM, LAD,CRC and RCA) to the lesions	Yes	Yes
Displaying the score in form of result tables/reports on paper and/or film	Yes	Yes
Pan and Zoom functionality/windowing	Yes	Yes
Reformatting	Yes	Yes
Comparison of Score to Cited Literature	Yes	Yes

The subject device syngo.CT CaScoring does not have changes in fundamental scientific technology compared to the predicate devices. The post-processing software functionality remains unchanged from the subject device and the predicate devices. The operating principle and the scientific technology are the same; therefore, Siemens believes that syngo.CT CaScoring application is substantially equivalent to the predicate devices.

VII. Performance Data

Software 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/Clinical Testing Summary
Performance tests were conducted to test the functionality of the syngo.CT CaScoring. 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.

General Safety and Effectiveness Concerns
The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing.

syngo.CT CaScoring is designed to fulfill the requirements of the following safety and performance 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
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	2/23/2016	IEC

For the new feature automated calcium scoring evaluation, a bench test has been conducted to show it performs as intended. The algorithm was successfully executed on all test data. An adequate overall accuracy of the prediction of the calcium risk category was found.

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT CaScoring to establish the proficiency of the 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.

VIII. Conclusions

syngo.CT CaScoring has the same intended use and similar indication for use as the predicate devices. The technological characteristics such as evaluation and documentation of calcified coronary lesions are the same 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 effective when compared to the predicate device that is currently marketed for the same intended use. For the subject device, syngo.CT CaScoring, Siemens used the same testing with the same workflows as used to clear the predicate device. Siemens considers syngo.CT CaScoring to be as safe, as effective and with performance substantially equivalent to the commercially available predicate devices.