Siemens Medical Solutions USA, Inc.
℅ Monsuru Bello
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

May 17, 2022

Re: K221219
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: April 25, 2022
Received: April 27, 2022

Dear Monsuru Bello:

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

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT 8B: 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)*

K221219

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 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 userdocumented 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.

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510(k) Summary

I. Identification of the Submitter

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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:	JAK

III. Predicate Device

Trade Name:	syngo.CT CaScoring
510(k) Number:	K201034
Clearance Date:	05/14/2020
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

The post-processing application syngo.CT CaScoring SOMARIS/8 VB70 is 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.

For the current software version SOMARIS/8 VB70 one major and one minor change have been implemented:

- Since the last 510(k) clearance of the predicate device (syngo.CT Calcium Scoring SOMARIS/8 VB50, K201034, clearance date 05/14/2020) the algorithm to precompute the calcium score has been enhanced. In the subject device, the CaScoring algorithm was re-trained on a larger database.
- This version contains UI (user-interface) modifications.

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 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

The differences and similarities between the above referenced predicate device are listed at a high-level in the following table:

Feature	**Subject Device**	**Predicate Devices**
	syngo.CT CaScoring (SOMARIS/8 VB70)	syngo.CT CaScoring (SOMARIS/8 VB50)
Modality	CT	CT
Loading of a series of appropriate CT from the patient database	Yes	Yes
Body Part	Heart / Chest	Heart / Chest
Acquisition Part	ECG-gated / ECG-triggered	ECG-gated / ECG-triggered
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. Each calcification is labeled according to one of four coronary arteries it most probably belongs to. In addition, results of the evaluation can be sent via Rapid Results Technology to any generic DICOM viewer. **Comparison to the predicate device:** The algorithm was re-trained on a larger database. A configuration option was added so the user can disable the 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. Each calcification is labeled according to one of four coronary arteries it most probably belongs to. In addition, results of the evaluation can be sent via Rapid Results Technology to any generic DICOM viewer.
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
Automatic definition of ROIs and assignment of a generic calcium label to the lesions	Yes	Yes
Calculation and display of the 2D-Agatston score/factor or other metric on the defined ROIs	Agatston, volume and mass scores	Agatston, volume and mass scores
Interactive definition of ROIs (for example noise) to disqualify the region from participation in the score	Yes	Yes
Displaying the score in form of result tables/reports on paper and/or film	Yes	Yes

Feature	Subject Device	Predicate Devices
	syngo.CT CaScoring (SOMARIS/8 VB70)	syngo.CT CaScoring (SOMARIS/8 VB50)
Pan and Zoom functionality/windowing	Yes	Yes
Reformatting	Yes	Yes
Comparison of Score to Cited Literature (including calculation of coronary age)	Yes	Yes
User Interface	syngo.via GUI	syngo.via GUI
Archiving/Storing	CD-R, film, DVD, USB, Network	CD-R, film, DVD, USB, Network
Hardware	As specified by syngo.via	As specified by syngo.via
Communication	DICOM compatible	DICOM compatible

The subject device syngo.CT CaScoring does not have changes in fundamental scientific technology compared to the predicate device. The post-processing software functionality remains unchanged from the subject device and the predicate device. The operating principle and the scientific technology are the same; therefore, Siemens believes that syngo.CT CaScoring application is substantially equivalent to the predicate device. The major change in this software version is that the *Automated Calcium Scoring Evaluation* algorithm has been re-trained on a larger database.

VII. Performance Data

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

Non-Clinical Testing

This submission contains performance tests (Non-clincal test reports) to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT CaScoring 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.

Performance Evaluation of the Algorithm

Since the automatic scoring algorithm was retrained on re-annotated data, a complete performance evaluation (bench test) of the algorithm has been conducted additionally. The algorithm was successfully executed on all testing datasets. No data has been excluded from the analysis. The summary of the bench test is that an adequate and acceptable performance of the automatic scoring algorithm was found for the total Agatston-equivalent score and the classification into the corresponding Agatston score categories, which are the aspects of calcium scoring that have a well-established impact on management recommendations. All pre-specified acceptability criteria were passed.

Risk Analysis

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 of the device was found acceptable to support the claims of substantial equivalence.

Siemens hereby certifies that syngo.CT CaScoring will meet the following voluntary standards covering electrical and mechanical safety listed below, prior to introduction into interstate commerce:

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; 62304:2015-06 (Edition 1.1)	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
5-129	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015 +AMD1:2020	07/06/2020	ANSI, AAMI, IEC
5-117	General I (QS/RM)	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements 15223-1:2016	8/21/2017	ISO

VIII. Conclusion

syngo.CT CaScoring has the same intended use and same indication for use as the predicate device. 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 device.