Siemens Medical Soultions USA, Inc.
% Ms. Veronica Padharia
Regulatory Affairs Specialist
2501 N. Barrington Road
HOFFMAN ESTATES IL 60192

March 25, 2020

Re: K200515
Trade/Device Name: syngo.CT Cardiac Planning
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: February 28, 2020
Received: March 2, 2020

Dear Ms. Padharia:

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)*
K200515

Device Name
syngo.CT Cardiac Planning

Indications for Use *(Describe)*
syngo.CT Cardiac Planning is an image analysis software package for evaluating contrast enhanced CT images. The software package is designed to support the physician in the qualitative and quantitative analysis of morphology and pathology of vascular and cardiac structures, with the overarching purpose of servicing as input for the planning of cardiovascular procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5
510(k) Summary

K200515

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:
Veronica Padharia
Regulatory Affairs Specialist, CNMT
Siemens Medical Solutions, Inc. USA
2501 N. Barrington Road
Hoffman Estates, IL 60192
Phone: (630) 877-5761
Fax: (847) 304-6023
email: veronica.padharia@siemens-healthineers.com

II. Device Name and Classification

Product Name:	syngo.CT Cardiac Planning
Propriety Trade Name:	syngo.CT Cardiac Planning
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 Cardiac Planning
510(k) Number:	K170221
Clearance Date:	04/21/2017
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

syngo.CT Cardiac Planning is an image analysis software package for evaluating contrast enhanced CT images. The software package is designed to support the physician in the qualitative and quantitative analysis of morphology and pathology of vascular and cardiac structures, with the overarching purpose of serving as input for planning of cardiovascular procedures.

syngo.CT Cardiac Planning includes tools that support the clinician at different steps during diagnosis, including reading and reporting. The user has full control of the reported measurements and images and is able to choose the appropriate function suited for their clinical need. Features included in this software that aid in diagnosis can be grouped in the following categories:

- Basic reading: commodity features that are commonly available on CT cardiac postprocessing workstations
- Advanced reading: additional features for increased user support during CT cardiac postprocessing.

V. Indications for Use

syngo.CT Cardiac Planning is an image analysis software package for evaluating contrast enhanced CT images. The software package is designed to support the physician in the qualitative and quantitative analysis of morphology and pathology of vascular and cardiac structures, with the overarching purpose of serving as input for planning of cardiovascular procedures.

VI. Comparison of Technological Characteristics with the Predicate Device

Siemens' syngo.CT Cardiac Planning post-processing software package is substantially equivalent to the following medical device in commercial distribution:

Predicate Device	FDA Clearance Number	FDA Clearance Date
syngo.CT Cardiac Planning	K170221	04/21/2017

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

Subject Device **syngo.CT Cardiac Planning** (SOMARIS/8 VB40)	**Predicate Device** **syngo.CT Cardiac Planning** (SOMARIS/8 VB20)	**Comparison Table**
TAVI Feature		
• Evaluation of the Aortic Root	• Evaluation of the Aortic Root	Same
• Curved Planar Reformation	• Curved Planar Reformation	Same
• Measurement Tools	• Measurement Tools	Correction of the measurement algorithm
• C-arm Angulation	• C-arm Angulation	Same

Subject Device **syngo.CT Cardiac Planning** (SOMARIS/8 VB40)	**Predicate Device** **syngo.CT Cardiac Planning** (SOMARIS/8 VB20)	**Comparison Table**
Other Features		
Basic Reading Functionality	Basic Reading Functionality	Same
Cardiac, Aortic Valve and Mitral Valve Planes	Cardiac, Aortic Valve and Mitral Valve Planes	Same
Review Marker	Review Marker	Same
Integrated Reporting	Integrated Reporting	Same
Heart Isolation	Heart Isolation	Same
Blood Pool Removal	Blood Pool Removal	Same
Image Processing and Evaluation	Image Processing and Evaluation	Same
Archiving / Storing	Archiving / Storing	Same
User Interface (syngo.via based GUI)	User Interface (syngo.via based GUI)	Same
Communication (DICOM)	Communication (DICOM)	Same

There are no differences between the subject device and the predicate device. The subject device does not introduce any new features or modification to already cleared features. The subject device provides an error correction that return the Cardiac Planning software to its original specifications. It is Siemens' opinion that syngo.CT Cardiac Planning—with the measurement tool error correction implemented—is substantially equivalent to the predicate device.

VII. Performance Data / Safety and Effectiveness

Performance data was provided in the form of Verification and Validation to support the substantial equivalence determination. V&V testing can be found within the Attachment 16 Section.

This submission contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management has been ensured via the risk analysis in compliance with ISO 14971 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product.

For this submission, the risk analysis was performed to ensure the risk control was 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 adheres to recognized and established industry standards for development including ISO 13485 and IEC 62304.

Verification and Validation activities demonstrate continued conformance with special controls for medical devices containing software, including assurance that functions work as designed, performance requirements and specifications have been met, and that all hazard mitigations have been fully implemented. Integration and Functional testing was conducted for syngo.CT Cardiac Planning during product development. In addition, testing was performed to ensure the corrective measures implemented within this submission meet the predetermined acceptance values. It is in Siemens' opinion that the results of these test activities demonstrate that the subject device performs as intended and the results were found acceptable to support the claim of substantial equivalence.

Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

Siemens hereby certifies that syngo.CT Cardiac Planning will meet the following FDA recognized standards 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; 62304:2006/A1:2016	01/14/2019	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971	06/27/2016	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. Statement Regarding Substantial Equivalence

There are no differences in the Indications for Use or Fundamental Technology Characteristics of the syngo.CT Cardiac Planning software as compared to the currently commercially available software (K170221).

Additionally, there have been no changes that raise any new issues of safety and effectiveness as compared to the predicate device, only modifications to already existing fundamental scientific technology to bring the system back to commercially cleared (K170221) specifications. Based on this information, as well as documentation in support of modifications made, it is Siemens' opinion that the syngo.CT Cardiac Planning software is substantially equivalent to the predicate device.