DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 21, 2017

Siemens Medical Solutions U.S.A., Inc.
% George Bauer
510(k) TPR Deputy Program Manager
TÜV SÜD America, Inc.
1775 Old Highway 8 NW, Ste 104
New Brighton, Minnesota 55112-1891

Re: K170221
Trade/Device Name: syngo.CT Cardiac Planning
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 20, 2017
Received: January 25, 2017

Dear Mr. Bauer:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

SIEMENS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

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 serving as input for 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.

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510(K) SUMMARY
FOR
SYNGO.CT CARDIAC PLANNING

Submitted by:
Siemens Healthcare GmbH
Computed Tomography (CT)
Siemensstr. 1
91301 Forchheim

Date Prepared: March 15, 2017

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.
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Establishment Registration Number
2240869

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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:	90JAK

III. Predicate Device

Trade Name:	syngo.CT Cardiac Function
510(k) Number:	K123585
Clearance Date:	December 20, 2012
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 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 post-processing workstations.
- **Advanced reading:** additional features for increased user support during CT cardiac post-processing.

The user can operate the application in basic reading mode only, or advanced reading if deemed appropriate for the clinical task.

If results are not as expected by the user (e.g. due to bad image quality caused by image artifacts, such as: noise, pacemaker artifacts, stair steps, wrong contrast timing, etc.), he or she can easily modify the computations or discard them and do a manual diagnosis. The corresponding information will be kept in the reporting object which is stored in the syngo.via database.

As syngo.CT Cardiac Planning is designed for cardiovascular analysis, there are minimal requirements regarding the loaded data. The application requires contrast-enhanced CT data in order to be able to delineate cardiac vasculature and valvular apparatuses, and/or segment the blood pool in the heart chambers properly. If the user loads data without contrast agent, the algorithms will not work properly. Then a clear visual feedback via a message box is provided. There are no further measurements and the algorithm stops the calculation. The user is asked to manually define the location of the annular plane and continue working from there. If that is not possible for the user, only an axial slice-based manual reading of the case can be performed in the application.

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

syngo.CT Cardiac Planning is a post-processing software application which provides a set of functions similar to functionality of provides by the predicate device. All measuring and visualization tools remain unchanged except the Valve Pilot feature, which offers an additive visualization possibility.

As core functionality, syngo.CT Cardiac Planning uses basic and advanced reading functionality for planning of cardiovascular procedures. This subject device reuses the algorithms and technology as provided in the predicate device.

Feature	**Subject Device**	**Predicate Device** *(K123585)*
Acquisition	Contrast enhanced images	Contrast enhanced images
Basic Readingy Functionality	• Basic Reading Functionality • Cardiac, Aortic Valve and Mitral Valve Planes • Review Marker • Integrated Reporting • Heart Isolation • Blood Pool Removal	• Basic Reading Functionality • Cardiac, Aortic Valve and Mitral Valve Planes • Review Marker • Integrated Reporting • Heart Isolation • Blood Pool Removal
Advanced Reading Functionality	• Valve Pilot *(extended)* • Batch Mode	• Valve Pilot • Batch Mode
Image Processing and Evaluation	thin/thick MPR, thin/thick MIP, VRT, 3D VRT; CPR	thin/thick MPR, thin/thick MIP, VRT, 3D VRT; CPR, Hybrid VRT
Platform	Commercially available standard PC with Windows 7 or higher	Commercially available standard PC with Windows XP or higher
Host System	syngo.via VB20	syngo.via VA20

VII. Performance Data

Software Verification and Validation Testing
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.

For the subject device non-clinical as well as bench-level tests have been conducted. Non-clinical tests are done on the verification level; bench-level tests are done on the validation level, such as installation-testing, configuration of DICOM-nodes, system compatibility testing and usability tests.

Non-Clinical Testing Summary
syngo.CT Cardiac Planning 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
5-95	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	06/27/2016	IEC
19-4	General II (ES/EMC)	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod)	07/09/2014	AAMI, ANSI

Performance tests were conducted to test the functionality of syngo.CT Cardiac Planning. 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. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

The following safety aspects are supported by the subject device as well as the predicate device:

- both subject and predicate devices are pure post-processing applications
- There are no direct or indirect patient-contacting components within the scope of the subject device as well as the predicate device
- both subject and predicate devices have to be used by trained persons only
- all image data are to be interpreted by trained personnel
- both subject device and predicate do not pose human beings into direct harms
- both subject and predicate devices do neither provide primarily diagnosis nor automated diagnostics interpretation capabilities
- both subject and predicate devices are supported by the separate platform syngo.via
- both subject and predicate devices use same algorithms for rendering and measurement
- the trained user has full control on any conducted step during the whole process

VIII. Conclusions

syngo.CT Cardiac Planning has the same intended use and similar indication for use as the predicate device. The technological characteristics such as image visualization, measurement, operating platform, 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 device was cleared based on non-clinical supportive information. The results of these tests demonstrate that the predicate device is 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, syngo.CT Cardiac Planning, Siemens used the same testing with the same workflows as used to clear the predicate device. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.CT Cardiac Planning testing supports a finding of substantial equivalence.