DEC 2 0 2012

510(K) SUMMARY
FOR
SYNGO.CT CARDIAC FUNCTION

Submitted by:

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway

Malvern, PA 19355

Date Prepared: November 16, 2012

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.

1. **Contact Person:**
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2. **Device Name and Classification**

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

3. **Substantial Equivalence:**
Siemens syngo.CT Cardiac Function post processing software package is substantially equivalent to the following medical devices in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens syngo.CT Cardiac Function	K110366	12/04/2011
Siemens syngo.CT Vascular Analysis	K112020	08/18/2011
Siemens syngo Aortic Valve Guide	K113027	11/22/2011

4. **Device Description:**
syngo.CT-Cardiac Function is a dedicated application for cardiac and vascular post processing. Accordingly, syngo.CT-Cardiac Function has been designed in order to support diagnosis of cardiovascular lesions with a particular focus on conditions affecting cardiac function.

syngo.CT Cardiac Function 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 into 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.

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.

5. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**
syngo.CT Cardiac Function is a post-processing software package which provides a combination of functionality similar to functionality provided by

the predicate devices. It uses the same data for evaluation as the predicate devices and provides results in the same format as the predicate devices.

As core functionality, syngo.CT Cardiac Function uses basic reading, image display and evaluation functionality as provided by the predicate device *syngo.CT Cardiac Function (K110366, clearance date12/04/2011)*. In addition to this core functionality, *syngo.CT Cardiac Function* provides workflow improvements to support the user in repetitive tasks and provides extended support for the visualization of first pass relative enhancement. Similar to the predicate devices, *syngo Aortic ValveGuide* (K113027, clearance date 11/22/2011) and *syngo.CT Vascular Analysis* (K112020, clearance date 08/18/2011), syngo.CT Cardiac Function enables the user to visualize the aortic root allowing the measurement of its morphological characteristics.

Accordingly, syngo.CT Cardiac Function has similar technological characteristics as the predicate devices. syngo.CT Cardiac Function uses current image processing algorithms in order to provide results that are substantially equivalent to those obtained with the predicate devices.

syngo.CT Cardiac Function is designed to be operated on syngo.via VA20 platform in a single or multi user environment.

6. Nonclinical Testing:

syngo.CT Cardiac Function is designed to fulfill the requirements of following standards:

- IEC 60601-1-6 : 2006; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: 2008 DICOM conformity is fully covered by syngo.via implementations.

Non clinical tests were conducted for syngo.CT Cardiac Function software package during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports 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.

7. **Indications for Use:**
syngo.CT Cardiac Function is an image analysis software package for evaluating CT images of the heart. Combining digital image processing and visualization tools (2D, 3D and 4D display of dynamic data), evaluation tools (structural and functional analysis of heart chambers and valves, and analysis of myocardial tissue) and reporting tools, the software package is designed to support the physician in determining the functional and morphological parameters of the heart chambers, heart valves and confirming the presence or absence of physician-identified myocardial disease and evaluation, documentation and follow-up of any such finding

8. **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.

9. **Conclusion as to Substantial Equivalence**
In summary, Siemens is of the opinion that the syngo.CT Cardiac Function software package does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Siemens Medical Systems, Inc.
% Mrs. Kimberly Mangum
51 Valley Stream Parkway
Malvern, PA 19355

Re: K123585
Trade/Device Name: syngo.CT Cardiac Function
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: November 14, 2012
Received: November 21, 2012

Dear Mrs. Mangum:

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.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

510(k) Number (if known): _K123585_____

Device Name: ***syngo.CT Cardiac Function***

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
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