



Food and Drug Administration
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Boulevard, Mail Code 65 1-A
MALVERN PA 19355

November 2, 2015

Re: K150713

Trade/Device Name: syngo.CT Myocardial Perfusion
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 18, 2015
Received: September 29, 2015

Dear Ms. 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. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Indications for Use

510(k) Number (if known)
K150713

Device Name
syngo.CT Myocardial Perfusion

Indications for Use (Describe)

The Siemens syngo.CT Myocardial Perfusion software package has been designed to evaluate perfusion of the myocardium.

The software can calculate blood flow, blood volume, and other hemodynamic parameters from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media.

It supports evaluation of regions of interest and the visual inspection of time attenuation curves.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.

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**510(k) SUMMARY
FOR
syngo.CT Myocardial Perfusion**

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

Date Prepared: September 18, 2015

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. General Information

Importer/Distributor:

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

Establishment Registration Number: 2240869

Manufacturing Facility:

Siemens AG
Medical Solutions
Siemens Str. 1
D-91301 Forchheim, Germany

Establishment Registration Number: 3004977335

2. Contact Person:

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Regulatory Affairs Specialist
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3. Device Name and Classification

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

4. Legally Marketed Predicate Device

| | |
|-----------------------------------|--|
| Trade Name: | syngo® Volume Perfusion CT Body |
| 510(k)#: | K092013 |
| Clearance Date: | July 17, 2009 |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Classification Regulation: | 21 CFR § 892.1750 |
| Device Class: | II |
| Product Code: | 90JAK |
| Recall Information: | This predicate device has not been the subject of any design related recalls |

5. Device Description:

syngo.CT Myocardial Perfusion is post-processing image analysis software that offers the quantitative analysis of dynamic CT data of the myocardium following the injection of contrast media. By providing information about myocardial blood flow and myocardial blood volume, syngo.CT Myocardial Perfusion allows the evaluation of potential perfusion disturbances in the myocardium due to coronary artery disease. This might aid in the assessment of the hemodynamic relevance of coronary stenosis

syngo.CT Myocardial Perfusion provides a fast simultaneous multi-slice calculation of the following perfusion parameter images:

- Myocardial blood flow (MBF) image
- Myocardial blood volume (MBV) image
- Flow Extraction Product (FE) image
- Perfused Capillary Blood Volume (PCBV) image
- Extravascular Extracellular Volume (EEV) image
- Time to Peak (TTP) image
- Time to Start (TTS) image
- Tissue Transit Time (TTT) image
- Myocardial Blood Flow Corrected (MBFC) image; this parameter map is a copy of the Myocardial blood flow (MBF) image

The following modifications have been made to the previously cleared predicate device syngo® Volume Perfusion CT Body (K092013, clearance date July 17, 2009):

1. New software version SOMARIS/8 VB10 which supports the following features:
 - a. Separation of the Myocardial Perfusion algorithm from Volume Perfusion CT Body into a stand-alone SW application called "syngo.CT Myocardial Perfusion"

- b. Migration of the Myocardial Perfusion application to the syngo.via client server Software platform (cleared in K123375)
 - c. Updated Graphical User Interface
 - d. Result Storage – Additional option to store image results as Enhanced CT
 - e. TAC Display - Parallel display of several time attenuation curves (TAC)
2. A modified Indication for Use which is specific to Myocardial Perfusion.

6. **Indications for Use**

The Siemens syngo.CT Myocardial Perfusion software package has been designed to evaluate perfusion of the myocardium.

The software can calculate blood flow, blood volume, and other hemodynamic parameters from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media.

It supports evaluation of regions of interest and the visual inspection of time attenuation curves.

7. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**

syngo.CT Myocardial Perfusion software package has the same intended use and operating principle as the predicate syngo[®] Volume Perfusion-CT Body (K092013, clearance date 06/17/2009). syngo.CT Myocardial Perfusion is a post-processing application operating on the syngo.via platform in a single or multi user environment.

syngo.CT Myocardial Perfusion does not have significant changes in technological characteristics when compared to the predicate device. The Indications for Use and fundamental scientific technology are similar. The subject device and the predicate device are the same in regards to:

- Application and Acquisition
- Motion Correction
- CT Scanning Mode
- Time Point Removal
- 4D Noise Reduction
- Organ Segmentation
- Arterial Input Function Definition
- Vessel Definition
- Region of Interest and Volume of Interest
- Archiving/Storage
- Communication – DISOM compatible.

The myocardial and body perfusion algorithms use a deconvolution algorithm to estimate the perfusion parameters. The algorithms differ in the parametric convolution kernel. Body perfusion uses an adiabatic approximation to the tissue homogeneity model. The parameter map calculation in myocardial perfusion is based on the Tofts' model. According to the different scanning modes, the registration is different. A global registration is used in body perfusion. This global registration for myocardial perfusion is applied after a preceding rigid registration that aligns the stitching slices. The same algorithms and registrations were used in the predicate device syngo[®] Volume Body Perfusion CT Body (K092013, clearance date July 17, 2009).

The following table shows the differences in technological characteristics between the subject device and the predicate device.

Subject and Predicate Device Compared Technological Characteristics

| Technological Characteristics of the Subject Device as Compared to the Predicate Device | | | |
|---|---|---|--|
| Feature | Subject Device syngo.CT Myocardial Perfusion | Predicate Device syngo [®] Volume Perfusion CT Body (K092013) | Comparison |
| Result Storage | Storage of all result images in the database as DICOM CT grayscale, color RGB, Enhanced CT | Storage of all result images in the database as DICOM CT grayscale, color RGB | The subject device has the additional option of saving images as Enhanced CT. Verification and Validation testing supports this modification. |
| TAC Display | Parallel display of several time attenuation curves | Display of a single time attenuation curve | The subject device can display multiple Time Attenuation Curves, instead of only one. Verification and Validation testing supports this modification. |
| User Interface | syngo.via based GUI | syngo [®] based GUI | The user interface has been adapted to the current syngo.via framework. Changes are cosmetic in nature. Verification and Validation testing supports this modification. |
| Operating Software Platform | syngo.via: Windows XP, Windows Vista or Windows 7 systems. Multiuser HW/SW architecture with client/server support | syngo [®] : Windows XP Professional or equivalent Single-user HW/SW architecture | syngo.via is a client/server multi-user framework and is further development of syngo [®] . It runs on updated Windows systems, and can support multiple users. Verification and Validation testing supports this modification. |

As the predicate device, syngo.CT Myocardial Perfusion uses scans of Siemens SOMATOM Definition Flash and Siemens SOMATOM Force scanners. These scanners are fast enough to acquire data of the left ventricle in the end systolic phase without motion. As the images are acquired in a single heart phase without motion, ECG gating is used to trigger the scans.

The detectors of these two scanners are not wide enough to scan the complete left ventricle in one scan, dedicated shuttle mode scans are used instead. These scans acquire the heart in two alternating slabs, scanning the upper and lower part of the heart. In between the scans the patient is moved. The scan protocols are described in Attachment 5 and 6 in more detail.

Currently two Siemens scanners (namely SOMATOM Definition Flash K082220, clearance date 10/10/08 the SOAMTOM Definition Flash and SOMATOM Force K133589, clearance date 04/17/2014), can provide data for CT Myocardial Perfusion. In the future scanners that are fast enough might be able to support scanning with a normal perfusion scan without shuttle because they are wide enough to scan the entire heart.

As syngo.CT Myocardial Perfusion is a post processing application only, it can use both types of data, normal perfusion data (non-shuttle mode) as well as shuttle mode data. The application was tested with both types, emulating the normal perfusion data by only using one of the slabs.

8. Nonclinical Testing:

Nonclinical tests were conducted for syngo.CT Myocardial Perfusion during product development. The modifications described in this premarket notification are supported with verification and validation testing. Results of this verification and validation testing were found acceptable to support the claim of substantial equivalence.

Siemens claims conformance to the following five safety and performance standards for syngo.CT Myocardial Perfusion.

| Title of Standard | Reference Number and Date | Publication Date | Standards Development Organization |
|---|---------------------------------|------------------|------------------------------------|
| Digital Imaging and Communications in Medicine (DICOM) Set | PS 3.1 – 3.18 | 03/16/2012 | NEMA |
| Medical device software – Software life cycle processes | 62304 First edition 2006-05 | 08/20/2012 | IEC |
| Medical devices – Application of risk management to medical devices | 14971 Second Edition 2007-03-01 | 08/20/2012 | ISO |

| Title of Standard | Reference Number and Date | Publication Date | Standards Development Organization |
|---|------------------------------------|------------------|------------------------------------|
| Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability | 60601-1-6 Edition 3.0 2010-01 | 1/30/2014 | IEC |
| Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1 | 60601-1-4:2000, Consol. Ed. 1.1 | 09/08/2009 | IEC |

Verification and Validation

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Integration and functional tests were conducted for syngo.CT Myocardial Perfusion during product development.

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. The test results show that all of the software specifications have met the acceptance criteria.

Siemens conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. It is the hospital’s responsibility to comply with IEC 8001-1-2010.

Summary

Performance tests were conducted to test the functionality of the subject device, syngo.CT Myocardial Perfusion. Supportive articles that demonstrate the usability of syngo.CT Myocardial Perfusion were provided to support device performance and functionality. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

9. 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.

10. Conclusion as to Substantial Equivalence

The predicate device was cleared based on non-clinical supportive information. The subject device non-clinical data supports the safety of the software with verification and validation testing. Verification and validation testing demonstrates that syngo.CT Myocardial Perfusion performs as intended. The non-clinical test data demonstrates that syngo.CT Myocardial Perfusion device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary, Siemens is of the opinion that the syngo.CT Myocardial Perfusion does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.