K100637

MAY 26 2010

Section 8

510(k) - Summary

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. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	*syngo.CT Coronary Analysis*
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 Erlangen, Germany

4. Contact Person:

Mr. Ralf Hofmann
Regulatory Affairs Specialist
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-8170
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: Nov. 16th 2009

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. 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 via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Substantial Equivalence:

syngo.CT Coronary Analysis software package, designed for post processing images that have been continuously acquired with computed tomography (CT) imaging systems which meet certain minimal requirements, is substantially equivalent to the following devices:

Manufacturer	Product	510(k)	Clearance date
1. Siemens AG	syngo® Circulation	K063762	01/05/2007
2. Siemens AG	syngo®.x	K092519	08/27/2009
3. GE Medical Systems	CardIQ Xpress 2.0	K073138	02/26/2008

8. Device Description and Intended Use:

Syngo.CT Coronary is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets.
Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), evaluation tools (coronary vessel centerline calculation, stenosis calculation and plaque analysis) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified coronary lesions and evaluation, documentation and follow-up of any such lesion. These visualization/evaluation tools allow for characterization of coronary lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Siemens AG, Medical Solutions
% Mr. Stefan Preiss
Official Third Party Official
TÜV SÜD America
1775 Old Highway 8 NW, Ste 104
NEW BRIGHTON MN 5112-1891

MAY 26 2010

Re: K100637
Trade/Device Name: syngo.CT Coronary Analysis
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 11, 2010
Received: May 14, 2010

Dear Mr. Preiss:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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* Diagnostic Device Evaluation and Safety 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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 2

Indication for use

510(k) Number (if known): _____

Device Name: **syngo.CT Coronary Analysis**

Syngo.CT Coronary is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets.
Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), evaluation tools (coronary vessel centerline calculation, stenosis calculation and plaque analysis) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified coronary lesions and evaluation, documentation and follow-up of any such lesion.
These visualization/evaluation tools allow for characterization of coronary lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

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

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100637