K133648
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JUL 07 2014

510(K) SUMMARY

FOR

syngo.CT Dual Energy Software Package

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: May 16, 2014

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.
   51 Valley Stream Parkway
   Malvern, PA 19355

   Establishment Registration Number:
   2240869

   Manufacturing Site:
   Siemens AG Medical Solutions
   Henkestraße 127
   D-91052 Erlangen, Germany

   Establishment Registration Number:
   3002808157

2. **Contact Person:**
   Kimberly Mangum
   Regulatory Affairs Technical Specialist
   Siemens Medical Solutions, Inc. USA
   51 Valley Stream Parkway, D02
   Malvern, PA 19355-1406
   Phone: (610) 448-1772
   Fax: (610) 448-1778
   Email: kimberly.mangum@siemens.com

3. **Device Name and Classification**

Product Name:	syngo.CT Dual Energy
Propriety Trade Name:	syngo.CT Dual Energy
Classification Name:	Computed Tomography X-ray System

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Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: 90JAK

Legally Marketed Predicate Devices
Trade Name: SOMATOM DRI X-Ray Scanner CT System
510(k)#: K837107
Clearance Date: March 09, 1983
Classification Name: System, X-Ray, Tomography, Computed
Classification Panel: Radiology
Classification Regulation: 21 CFR § 892.1750
Device Class: II
Product Code: JAK

Trade Name: syngo® Dual Energy with extended functionality
510(k)#: K083524
Clearance Date: April 01, 2009
Classification Name: System, X-Ray, Tomography, Computed
Classification Panel: Radiology
Classification Regulation: 21 CFR § 892.1750
Device Class: II
Product Code: JAK

4. Substantial Equivalence:
The subject device syngo.CT Dual Energy software package is substantially equivalent to following medical devices in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
syngo® Dual Energy Software Package	K083524	April 1, 2009
SOMATOM DRI X-Ray Scanner CT System	K837107	March 09, 1983

5. Device Description:
Dual energy offers functions for qualitative and quantitative evaluations. Dual energy CT can be used to improve the visualization of the chemical composition of various energy dependent materials in the human body when compared to single energy CT.

Depending on the organ of interest, the user can select and modify different application classes or parameters and algorithms. syngo.CT Dual Energy Software Package is a post processing application package consisting of several post processing application classes that can be used to improve visualization of various energy dependent materials in the human body.

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syngo.CT Dual Energy is a post processing software package designed to operate on the most recent version syngo:via client server platform, which supports preprocessing and loading of datasets by syngo.via depending on configurable rules. Similar to the predicate device (K083524, clearance date April 01, 2009), syngo.CT Dual Energy allows the evaluation of CT data acquired via spiral or sequence scans at two sufficiently different energy spectra (for example 80 kV and 140 kV) achieved with dual source CT scanners.

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

syngo.CT Dual Energy Software Package is a post processing application operating on the multi-user syngo.via client server platform. The subject syngo.CT Dual Energy provides similar evaluation, reporting and visualization tools, and functionality as the predicate device syngo® Dual Energy This includes image processing and visualization tools such as basic visualization of various energy dependent materials in the human body and VRT visualization. In addition to the previously cleared dual energy applications, syngo.CT Dual energy supports the following dual energy application classes:

- Monoenergetic Plus
- Virtual Unenhanced
- Bone Marrow

syngo.CT Dual Energy does not have significant changes in technological characteristics when compared to the predicate device syngo® Dual Energy. The Indication for Use, operating principle, and the scientific technology are similar; therefore, Siemens believes that syngo.CT Dual Energy Package is substantially equivalent to the predicate devices.

7. **Nonclinical Testing:**

syngo.CT Dual Energy Software Package is designed to fulfill the requirements of following standards:

- IEC 60601-1-6 : 2007; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 60601-1-4:2000; Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1
- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices

- Digital Imaging and Communications in Medicine (DICOM) Set Standard: 2008 DICOM conformity is fully covered by syngo.via implementations.

Phantom bench tests have been conducted in the case of Monoenergetic Plus as well as a retrospective analysis of available patient data from several hospitals for all three new application classes.

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.

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.

8. **Indications for Use:**
syngo.CT Dual Energy is designed to operate with CT images which have been acquired with Siemens Dual Source scanners. The various materials of an anatomical region of interest have different attenuation coefficients, which depend on the used energy. Depending on the region of interest, contrast agents may be used. These differences provide information on the chemical composition of the scanned body materials. syngo.CT Dual Energy combines images acquired with low and high energy spectra to visualize this information.

The functionality of the syngo.CT Dual Energy applications is as follows:

- Monoenergetic
- Brain Hemorrhage
- Gout Evaluation
- Lung Vessels
- Heart PBV
- Bone Removal
- Lung Perfusion
- Liver VNC
- Monoenergetic Plus
- Virtual Unenhanced
- Bone Marrow
- Kidney Stones*)

*) Kidney Stones is designed to support the visualization of the chemical composition of kidney stones and especially the differentiation between uric acid and non-uric acid stones. For full identification of the kidney stone additional clinical information should be considered such as patient history and urine testing. Only a well-trained radiologist can make the final diagnosis under consideration of all available information. The accuracy of identification is decreased in obese patients.

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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

In summary, Siemens is of the opinion that the syngo.CT Dual Energy 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 20993-0002

July 7, 2014

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Technical Specialist, Regulatory Submissions
51 Valley Stream Parkway, D02
MALVERN PA 19355

Re: K133648
Trade/Device Name: syngo.CT Dual Energy
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 20, 2014
Received: June 23, 2014

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.

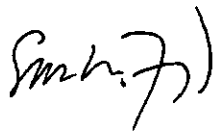
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

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

Enclosure

510(k) Number (if known): K133648

Device Name: syngo.CT Dual Energy

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

(Division Sign Off)

Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

510(k) K133648