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

February 9, 2017

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

Re: K163289
Trade/Device Name: syngo.CT Single Source Dual Energy (twin beam)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 22, 2016
Received: November 23, 2016

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

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)*
K163289

Device Name
syngo.CT Single Source Dual Energy (twin beam)

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

The functionality of the syngo.CT Single Source Dual Energy applications are as follows:
- Monoenergetic
- Bone Removal
- Liver VNC
- Lung Analysis
- Gout Evaluation
- Monoenergetic Plus
- Virtual Unenhanced
- Rho/Z
- Hard Plaques
- 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SIEMENS

510(K) SUMMARY
FOR
SYNGO.CT SINGLE SOURCE DUAL ENERGY (TWIN BEAM)

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

Date Prepared: November 09, 2016

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.
40 Liberty Boulevard
Malvern, PA 19355

Establishment Registration Number
2240869

Manufacturing Site
Siemens Healthcare GmbH
Siemensstr. 1
D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Contact Person
Kimberly Mangum
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Phone: (610) 448 - 6477
Fax: (610) 640 - 4481
Email: kimberly.mangum@siemens.com

II. Device Name and Classification

Product Name:	syngo.CT Single Source Dual Energy (twin beam)
Propriety Trade Name:	syngo.CT Single Source Dual Energy (twin beam)
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

Primary Predicate Device:

Trade Name:	syngo.CT Single Source Dual Energy (twin beam)
510(k) Number:	K153220
Clearance Date:	02/19/2016

SIEMENS

Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK
Recall:	There have been no recalls for this device

Secondary Predicate Device:

Trade Name:	syngo.CT Dual Energy
510(k) Number:	K150757
Clearance Date:	08/11/2015
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	90JAK
Recall:	There have been no recalls for this device

IV. 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 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 Single Source Dual Energy (twin beam) 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. This software application is 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.

After loading the two reconstructed image datasets acquired with two different X-ray spectra into syngo.CT Single Source Dual Energy (twin beam), a correction algorithm is used in order to minimize motion effects. They are then displayed using linear blending with selectable mixing ratio and color scale. Multiplanar reformations (MPR) of the volume are shown in 3 image segments, which are initialized as sagittal, coronal and axial view. After arriving at an initial diagnosis on the basis of the CT-images, the user can choose one of the following application classes:

- Monoenergetic
- Bone Removal
- Liver VNC
- Lung Analysis
- Gout Evaluation
- Monoenergetic Plus
- Virtual Unenhanced
- Rho/Z
- Hard Plaques
- Kidney Stones

These application classes are designed for specific clinical tasks, so that algorithms, additional tool buttons, the use of colored overlay images and image representation (for example MPR or maximum intensity projection) is optimized correspondingly. A listing of major device modifications within the scope of the new software version SOMARIS 8/VB20 is as follows:

- The Use of Twin Beam Images for additional Dual Energy post-processing Applications *(Lung Analysis and Gout)*
- Modified Indications for Use Statement

An additional modification is the support of Offline Ranges for Dual Energy which allows the user to select the required post-processing for reconstructed Dual Energy image series at the scanner.

SIEMENS

V. Indications for Use

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

The functionality of the syngo.CT Single Source Dual Energy applications are as follows:

- Monoenergetic
- Bone Removal
- Liver VNC
- Lung Analysis
- Gout Evaluation
- Monoenergetic Plus
- Virtual Unenhanced
- Rho/Z
- Hard Plaques
- 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.

VI. Comparison of Technological Characteristics with the Predicate Device

syngo.CT Single Source Dual Energy (twin beam) Software Package is a post-processing application operating on the multi-user syngo.via client/server platform. The subject syngo.CT Single Source Dual Energy (twin beam) provides the same evaluation, reporting and visualization tools, and functionality as the primary predicate device. This includes image processing and visualization tools such as basic visualization of various energy dependent materials in the human body and VRT visualization. Compared to the secondary predicate device, the aforementioned evaluation reporting and visualization tools and functionality as well as the post-processing algorithms remain unchanged.

Feature	**Subject Device**	**Primary Predicate Device** *(K153220)*	**Secondary Predicate Device** *(K150757)*
Data Acquisition Mode	The subject device uses DICOM images acquired using Twin Beam (split filtration) Single Source scanners.	The primary predicate device uses DICOM images acquired using Twin Beam (split filtration) Single Source scanners.	This device uses DICOM images acquired with Dual Source scanners.
Image Processing	The software processes Twin Beam Dual Energy images.	The software processes Twin Beam Dual Energy images.	The software processes Dual Source Dual Energy images.
Functionality	Post-processing application supports the use of Twin Beam datasets with various post-processing applications. Here, two additional (Gout Evaluation and Lung Analysis) post-processing applications are able to process twin beam images.	Post-processing application supports the use of Twin Beam datasets with various post-processing applications.	Post processing application supports the use of Dual Source datasets with various post processing applications

Feature	Subject Device	Primary Predicate Device *(K153220)*	Secondary Predicate Device *(K150757)*
Application Class "*Gout Evaluation*"	The Dual Energy information can be used to visualize urate, calcifications and contrast agent in the case of gout. The basis for this approach is a material decomposition into tissue and uric acid deposits. The results of this calculation are shown as color overlay to anatomical, grayscale information. This application class evaluates images acquired with Siemens Twin Beam Scanners. The post-processing functionality has not been changed compared to the secondary predicate device.	N/A	The Dual Energy information can be used to visualize urate, calcifications and contrast agent in the case of gout. The basis for this approach is a material decomposition into tissue and uric acid deposits. The results of this calculation are shown as color overlay to anatomical, grayscale information. This application class evaluates images acquired with Siemens Dual Source Scanners.
Application Class "*Lung Analysis*	This application class is designed to visualize the iodine enhancement in pulmonary vessels and visualize and quantify the iodine uptake in the lung parenchyma. This application class evaluates images acquired with Siemens Twin Beam Scanners. The post-processing functionality has not been changed compared to the secondary predicate device.	N/A	This application class is designed to visualize the iodine enhancement in pulmonary vessels and visualize and quantify the iodine uptake in the lung parenchyma. This application class evaluates images acquired with Siemens Dual Source Scanners.

The subject device syngo.CT Single Source Dual Energy (twin beam) does not have changes in technological characteristics when compared to the predicate devices. The post-processing software functionality remains unchanged from the subject device and the predicate devices. The operating principle and the scientific technology are same; therefore, Siemens believes that syngo.CT Single Source Dual Energy (twin beam) application is substantially equivalent to the predicate devices.

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.

Non-Clinical / Clinical Testing Summary
syngo.CT Single Source Dual Energy (twin beam) 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

Recognition Number	Product Area	Title of Standard	Publication Date	Standards Development Organization
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 the syngo.CT Single Source Dual Energy (twin beam) post-processing application. A clinical validation has been conducted to show that both application classes “Gout” and “Lung Analysis” operate as intended. We have shown that this software application based on Twin Beam Dual Energy data successfully visualizes urate depositions as a consequence of gout. The second validation shows that the application class Lung Analysis for Twin Beam data successfully calculates Lung PBV and Lung Vessels images from contrast enhanced Dual Energy CT-scans of the lung. Both application classes do not offer additional or new application features compared to the secondary predicate device.

Furthermore, phantom bench testing and clinical validation in a retrospective study was conducted to test the functionality of the remaining application classes Rho/Z and Kidney Stones. Retrospective clinically validated studies were conducted to test the performance for applications classes Monoenergetic Plus, Bone Removal, Liver VNC, and Hard Plaques, as well as the predicate device application classes. These studies demonstrate that the subject device using twin beam datasets performs as well as the predicate device applications that were tested using the same methods.

Supportive articles that demonstrate the usability of the application classes were provided to support device performance and functionality. 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.

VIII. Conclusions

syngo.CT Single Source Dual Energy (twin beam) has the same intended use and similar indication for use as the predicate devices. The technological characteristics such as image visualization, operating platform, and image manipulation are the same as the predicate devices. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The predicate devices were cleared based on non-clinical supportive information and clinical images. The results of these tests demonstrate that the predicate devices are 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 devices that are currently marketed for the same intended use. For the subject device, syngo.CT Single Source Dual Energy (twin beam), Siemens used the same testing with the same workflows as used to clear the primary predicate device. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.CT Single Source Dual Energy (twin beam) testing supports a finding of substantial equivalence.