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

August 11, 2015

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

Re: K150745
Trade/Device Name: syngo.CT Single Source Dual Energy
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 24, 2015
Received: July 8, 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.
Acting 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

Indications for Use

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

510(k) Number *(if known)*
K150745

Device Name
syngo.CT Single Source Dual Energy

Indications for Use *(Describe)*
Syngo.CT Single Source Dual Energy is designed to operate with CT images which have been acquired with Siemens Dual Spiral 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 is as follows:
• Monoenergetic
• Monoenergetic Plus
• Brain Hemorrhage
• Liver VNC
• Gout Evaluation
• Bone Marrow
• Rho/Z
• 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.

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"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."

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510(K) SUMMARY
FOR
syngo.CT Single Source Dual Energy

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Date Prepared: June 24, 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 Establishment:
   Registration No: 2240869
   Siemens Medical Solutions USA, Inc.
   51 Valley Stream Parkway
   Malvern, PA 19355

   Manufacturing Facility:
   Siemens AG
   Medical Solutions
   Siemens Str. 1
   D-91301 Forchheim, Germany
   Establishment Registration Number:
   3004977335

2. **Contact Person:**
   Kimberly Mangum
   Regulatory Affairs Specialist
   Siemens Medical Solutions, Inc. USA
   51 Valley Stream Parkway, Mail Code D02
   Malvern, PA 19355
   Phone: (610) 448-4912
   Fax: (610) 448-1787
   Email: kimberly.mangum@siemens.com

3. **Device Name and Classification**

Product Name:	syngo.CT Single Source Dual Energy
Propriety Trade Name:	syngo.CT Single Source Dual Energy (dual spiral)
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

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4. Legally Marketed Primary Predicate Device:

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

Legally Marketed Secondary Predicate Device

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

Product Name:	SOMATOM DRI X-Ray CT Scanner
Propriety Trade Name:	SOMATOM DRI X-Ray CT Scanner
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	90JAK

5. Indications for Use

syngo.CT Single Source Dual Energy is designed to operate with CT images which have been acquired with Siemens Dual Spiral 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 Dual Energy applications is as follows:

- Monoenergetic
- Monoenergetic Plus
- Brain Hemorrhage
- Liver VNC
- Gout Evaluation
- Bone Marrow
- Rho/Z
- 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.

6. Substantial Equivalence:

The subject device Siemens syngo.CT Single Source Dual Energy is substantially equivalent to following medical devices in commercial distribution as listed in **Table 1**:

Table 1: Predicate Devices

Manufacturer	Predicate Device	510(k)	Clearance Date
Siemens	**Primary Predicate Device:** syngo.CT Dual Energy	K133677	October 16, 2014
Siemens	**Secondary Predicate Device:** syngo.CT Dual Energy	K133648	July 07, 2014
Siemens	**Secondary Predicate Device:** SOMATOM DRI X-ray Scanner	K837107	March 9, 1983

7. 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 Single Source 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.

Different body regions require specific tools that allow for the correct evaluation of data sets. syngo.CT Single Source Dual Energy provides a range of application classes that meet the requirements of each evaluation type. The different application classes for the subject device can be combined into one workflow. A listing of device modifications is as follows:

1. New software version syngo.via VB10 (SOMARIS/8 VB10A) for the syngo.CT Single Source Dual Energy post processing application package to support the following features:
    - Addition of new application class Rho/Z
    - Visualization of fat content (fat map) for application class Liver VNC
2. Modified Indication for Use to include features Rho/Z
3. Modified Indication for Use to include reference to Dual Spiral Single Source Scanners

The subject device syngo.CT Single Source Dual Energy also supports the following unmodified post-processing application classes:

- Monoenergetic
- Brain Hemorrhage
- Gout Evaluation
- Monoenergetic Plus
- Bone Marrow
- Kidney Stones

syngo.CT Single Source Dual Energy 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.

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

syngo.CT Single Source Dual Energy Software Package is a post processing application operating on the most recent version of the syngo.via client server platform. The subject device syngo.CT Single Source Dual Energy provides similar evaluation, reporting and visualization tools, and functionality as the primary predicate device syngo.CT Single Source Dual Energy, and secondary predicate devices. This includes image processing and visualization tools such as basic visualization of various energy dependent materials in the human body and VRT visualization. **Table 2** below provides a comparison of the primary features of the subject device in comparison to the predicate devices.

Table 2: Predicate and Subject Device Comparable Technological Characteristics

Property	Subject Device	Primary Predicate Device K133677	Secondary Predicate Device K133648	Secondary Predicate Device K837107
Software Features/ Functionality	**Rho/Z** - Measurement of electron density as well as effective atomic number	Not Applicable	Base material decomposition into tissue and iodine	Visualization - Electron Density Visualization Features
	Liver VNC - Visualization of fat content	Fat content result in the calculation of Virtual Non Contrast (VNC) images	Fat content result in the calculation of Virtual Non Contrast (VNC) images	Not Applicable

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

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9. Nonclinical Testing:

syngo.CT Single Source Dual Energy is designed to fulfill the requirements of the following safety and performance standards listed in **Table 5** below:

Table 5: Conformance Standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
12-238	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20	03/16/2012	NEMA
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	08/20/2012	ISO
5-85	General	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	07/09/2014	IEC
5-41	General	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

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) were conducted for syngo.CT Single Source Dual Energy during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

The risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support 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 Verification and Validation

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.

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Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of the syngo.CT Single Source Dual Energy. Phantom bench testing and retrospective analysis of available patient data was conducted for application classes Rho/Z and feature Fat Map. Supportive articles that demonstrate the usability of application class Rho/Z and feature Fat Map for Liver VNC 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.

10. 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.

11. Conclusion as to Substantial Equivalence

syngo.CT Single Source Dual Energy has the same intended use and comparable indication for use as the predicate devices. The technological characteristics such as image visualization, operating platform, and image manipulation are similar to the predicate devices. Any differences in technological characteristics between the subject device and the predicate devices do not raise different questions of safety or effectiveness. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

The predicate devices were cleared based on non-clinical supportive information including phantom bench test, retrospective review of available patient data, and supportive clinical articles. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The same testing and workflows were used to test the subject device modifications. 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. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.CT Single Source Dual Energy testing supports a finding of substantial equivalence.