



Siemens Medical Solutions, USA, Inc.  
% Ms. Cynthia Busch  
Regulatory Affairs Specialist  
2501 N. Barrington Road  
HOFFMAN ESTATES, IL 60192

July 3, 2019

Re: K191468  
Trade/Device Name: syngo.CT Dual Energy  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: Class II  
Product Code: JAK  
Dated: May 29, 2019  
Received: June 3, 2019

Dear Ms. Busch:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

<https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Division Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K191468

Device Name  
syngo.CT Dual Energy

### Indications for Use (Describe)

syngo.CT Dual Energy is designed to operate with CT images based on two different X-ray spectra.

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 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 general functionality of the syngo.CT Dual Energy application is as follows:

- Monoenergetic
- Brain Hemorrhage
- Gout Evaluation
- Lung Vessels
- Heart PBV
- Bone Removal
- Lung Perfusion
- Liver VNC
- Monenergetic Plus
- Virtual Unenhanced
- Bone Marrow
- Hard Plaques
- Rho/Z
- Kidney Stones\*
- SPR (Stopping Power Ratio)
- SPP (Spectral Post-Processing Format)

The availability of each feature is depending on the Dual Energy scan mode.

\*)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 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.**

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**510(k) SUMMARY**  
**FOR**  
**SYNGO.CT DUAL ENERGY**  
as required by 21 CFR Part 807.87(h)  
**K191468**

**I. Identification of the Submitter**

**Importer/Distributor**

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

**Establishment Registration Number**  
2240869

**Manufacturing Site**

Siemens Healthcare GmbH  
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**Establishment Registration Number**  
3004977335

**Submitter Contact Person:**

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**Alternate Contact Person:**

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Regulatory Project Manager  
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Email: alaine.medio@siemens-healthineers.com

**Date of Submission :** May 29, 2019

**II. Device Name and Classification**

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: 90 JAK

### III. Predicate Device

**Primary 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: 90 JAK  
Recall: There have been no recalls for this device

**Reference Predicate Device:**

Trade Name: syngo.CT Single Source Dual Energy  
510(k) Number: K150745  
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: 90 JAK  
Recall: There have been no recalls for this device

**Reference Predicate Device:**

Trade Name: syngo.CT Single Source Dual Energy (twin beam)  
510(k) Number: K163289  
Clearance Date: 02/09/2017  
Classification Name: Computed Tomography X-ray System  
Classification Panel: Radiology  
CFR Section: 21 CFR § 892.1750  
Device Class: Class II  
Product Code: 90 JAK  
Recall: There have been no recalls for this device

### IV. Device Description

Dual energy offers functions for qualitative and quantitative post-processing 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 Dual Energy is a post-processing application 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.

- |                     |   |
|---------------------|---|
| 1. Monoenergetic    | 9. Monoenergetic Plus                     |
| 2. Brain Hemorrhage | 10. Virtual Unenhanced                    |
| 3. Gout Evaluation  | 11. Bone Marrow                           |
| 4. Lung Vessels     | 12. Hard Plaques                          |
| 5. Heart PBV        | 13. Rho/Z                                 |
| 6. Bone Removal     | 14. Kidney Stones                         |
| 7. Lung Perfusion   | 15. SPR (Stopping Power Ratio)            |
| 8. Liver VNC        | 16. SPP (Spectral Post-Processing format) |

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.

### Modifications

syngo.CT Dual Energy modifications with software version SOMARIS/8 VB40 are as follows:

1. The merge of the three already cleared post-processing Dual Energy applications into one application called syngo.CT Dual Energy:
  - syngo.CT Dual Energy (e.g. K150757, clearance date 08/11/2015),
  - syngo.CT Single Source Dual Energy (e.g. K150745, clearance date 08/11/2015)
  - syngo.CT Single Source Dual Energy (twin beam) (e.g. K163289, clearance date 02/09/2017)
2. Update of the Indications for Use statement because of the aforementioned combination
3. Enhancement to image output and alternate image format:
  - SPP (Stopping Power Ratio)
  - SPR (Spectral Post-Processing Format)
4. Workflow Improvements:
  - Provide Dual Energy results with Rapid Results Technology for other Workflows.
  - Provide Dual Energy results as input for other rapid results technology types.

### V. Indications for Use

syngo.CT Dual Energy is designed to operate with CT images based on two different X-ray spectra.

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 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 general functionality of the syngo.CT Dual Energy application is as follows:

1. Monoenergetic
2. Brain Hemorrhage
3. Gout Evaluation
4. Lung Vessels
5. Heart PBV
6. Bone Removal
7. Lung Perfusion
8. Liver VNC
9. Monoenergetic Plus
10. Virtual Unenhanced
11. Bone Marrow
12. Hard Plaques
13. Rho/Z
14. Kidney Stones\*
15. SPR (Stopping Power Ratio)
16. SPP (Spectral Post-Processing Format)

The availability of each feature is depending on the Dual Energy scan mode.

\*) 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 Dual Energy is a post-processing application operating on the multi-user syngo.via client/server platform. The subject syngo.CT Dual Energy provides the same evaluation, reporting and visualization tools, and functionality as the 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.

The differences between the above referenced predicate devices are described at a high-level in the next table below:

	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	
Feature	Siemens syngo,CT Dual Energy	Siemens syngo.CT Dual Energy (K150757)	Siemens syngo.CT Single Source Dual Energy (K150745)	Siemens syngo.CT Single Source Dual Energy (twin beam) (K163289)	Comparison Results
<b>Input Data</b>					



Feature	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	Comparison Results
	Siemens syngo.CT Dual Energy	Siemens syngo.CT Dual Energy (K150757)	Siemens syngo.CT Single Source Dual Energy (K150745)	Siemens syngo.CT Single Source Dual Energy (twin beam) (K163289)	
<b>Data Acquisition Mode</b>	The subject device unifies all three data acquisition modes acquiring images from Dual Source scanners, Dual Energy Single Source, and Twin Beam scanners.	The software analyzes Dual Source Dual Energy images acquired with Dual Source scanners.	The software analyzes Dual Spiral Dual Energy images acquired with Dual Spiral Single Source scanners.	The software analyzes Twin Beam Dual Energy images acquired with Twin Beam Single Source scanners.	<b>Equivalent</b>  The subject device data acquisition mode supports all acquisition modes of the three predicates: single source and dual source scanner image acquisitions.
<b>Image Processing and Evaluation</b>	MPR, MIP, VRT, thick MPR, thin MIP, fused VRT, tinted VRT	MPR, MIP, VRT, thick MPR, thin MIP, fused VRT, tinted VRT	MPR, MIP, VRT, thick MPR, thin MIP, fused VRT, tinted VRT	MPR, MIP, VRT, thick MPR, thin MIP, fused VRT, tinted VRT	<b>Same</b>
<b>Provide Dual Energy results also as input for other Rapid Results Technology types</b>	Dual Energy result images generated with Rapid Results Technology can be used as input for other types of Rapid Results Technology (e.g. organ ranges).	The output images from all Dual Energy application classes can manually be processed on syngo.via with the available platform tools (e.g. organ ranges).	The output images from all Dual Energy application classes can manually be processed on syngo.via with the available platform tools (e.g. organ ranges).	The output images from all Dual Energy application classes can manually be processed on syngo.via with the available platform tools (e.g. organ ranges).	<b>Extended</b>  The subject device improves workflow but does not change the results that can be generated.
<b>Provide Dual Energy results with Rapid Results Technology also for other Workflows.</b>	The generation of Dual Energy automatic archiving ranges is separated from the Dual Energy application and can be obtained for any syngo.via workflow.	The generation of Dual Energy automatic archiving ranges is only possible within the Dual Energy workflow.	The generation of Dual Energy automatic archiving ranges is only possible within the Dual Energy workflow.	The generation of Dual Energy automatic archiving ranges is only possible within the Dual Energy workflow.	<b>Extended</b>  The subject device improves workflow but does not change the results that can be generated.

Feature	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	Comparison Results
	Siemens syngo.CT Dual Energy	Siemens syngo.CT Dual Energy (K150757)	Siemens syngo.CT Single Source Dual Energy (K150745)	Siemens syngo.CT Single Source Dual Energy (twin beam) (K163289)	
<b>SPR (Stopping Power Ratio)</b>	The Rapid Result Technology output type SPR allows for the calculation of stopping power images, which show the expected energy loss of protons in the material at each voxel position.	The application class Rho/Z provides all the necessary information that enables simple calculation of SPR-images. These images can be calculated offline by starting from Rho-images and applying a very small correction based on Z.	The application class Rho/Z provides all the necessary information that enables simple calculation of SPR-images. These images can be calculated offline by starting from Rho-images and applying a very small correction based on Z.	N/A – not supported by a TwinBeam scan.	<b>Extended</b>  The subject device merges the output images of an already cleared algorithm in a simple way.
<b>SPP (Spectral Post-Processing Format)</b>	syngo.CT Dual Energy uses low/high energy images for all calculations. Together with intermediate processing results these images can be stored in SPP images and also extracted from them.	syngo.CT Dual Energy uses low/high energy images for all calculations. Intermediate processing results are stored as separate series in the database.	syngo.CT Dual Energy uses low/high energy images for all calculations. Intermediate processing results are stored as separate series in the database.	syngo.CT Dual Energy uses low/high energy images for all calculations. Intermediate processing results are stored as separate series in the database.	<b>Similar</b>  An alternative image format is introduced, which contains the same information as images series that were previously available.

The subject device syngo.CT Dual Energy does not have changes in fundamental scientific technology 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 Dual Energy 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 Dual Energy 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 (1 <sup>st</sup> Edition)	08/20/2012	AAMI, ANSI, IEC
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

Performance tests were conducted to test the functionality of the syngo.CT Dual Energy post-processing application. A phantom-based validation has been conducted to show that both features SPR (Stopping Power Ratio) and SPP (Spectral Post-Processing Format) operate as intended.

For SPR, the report shows that the SPR feature can reproduce the theoretical SPR values of the phantom inserts used from Dual Energy CT scans. The evaluation is described and validated in the report *“Detailed Description of the DE application “DirectSPR“ as part of the medical product “Syngo.CT Dual Energy”, Version VB40”*.

Regarding the SPP evaluation, the combination of the SPP-generation process produces equivalent results to the reference method based on functionality available in the predicate device(s). This means also that the information in the SPP-format (including all hidden data) was correctly calculated. Hence, two new modules introduced to support the new SPP data format, “SPP Generation Unit” and “ISI Preparation Unit”, which are part of syngo.CT Dual Energy are working as specified. The evaluation is described and evaluated in the report *“Detailed Description and Bench Tests for the Feature “SPP/ISI””*.

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 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 are provided to support device performance and functionality.

Non-clinical tests and clinical validation have been conducted to establish the proficiency of the 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 Dual Energy 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 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 Dual Energy, Siemens used the same testing with the same workflows as used to clear the primary predicate device. Siemens considers syngo.CT Dual Energy to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate devices.