March 28, 2022

Siemens Medical Solutions USA Inc.
% Clayton Ginn
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

Re: K212889
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: February 24, 2021
Received: February 25, 2021

Dear Clayton Ginn:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Diagnostic X-ray Systems Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212889

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 1)
- Brain Hemorrhage
- Gout Evaluation
- Lung Vessels
- Heart PBV
- Bone Removal
- Lung Perfusion
- Liver VNC
- Monoenergetic Plus 1)
- Virtual Unenhanced 1)
- Bone Marrow
- Hard Plaques
- Rho/Z
- Kidney Stones 2)
- SPR (Stopping Power Ratio)
- SPP (Spectral Post-Processing Format) 1)
- Optimum Contrast 1)

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

1) This functionality supports data from Photon-Counting CT scanners.

2) 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 upon 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

K212889

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
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Submitter Contact Person:
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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:	JAK

III. Predicate Device

Trade Name:	syngo.CT Dual Energy
510(k) Number:	K191468
Clearance Date:	07/03/2019
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology

CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

IV. Device Description

Dual energy offers functions for qualitative and quantitative post-processing evaluations. syngo.CT Dual Energy is a post-processing application consisting of several post-processing application classes that 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.

Different body regions require specific tools that allow the correct evaluation of data sets. syngo.CT 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.

Modifications

A listing of device modifications for the software version SOMARIS/8 VB60 is as follows:

- SPP data from Siemens Photon Counting Computed Tomography (PCCT) data can be loaded into syngo.CT Dual Energy. For PCCT data, monoenergetic images at 70keV are shown for initial reading instead of the mixed images used for the scan modes Dual Source, Twin Beam, and Twin Spiral. The application classes Virtual Unenhanced and Monoenergetic Plus are supported for PCCT data.

There are no relevant changes for the three DE scan modes Dual Source, Twin Beam, and Twin Spiral.

V. Indications for Use

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- Hard Plaques
- Rho/Z

- Kidney Stones[2)]
- SPR (Stopping Power Ratio)
- SPP (Spectral Post-Processing Format)[1)]
- Optimum Contrast[1)]

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

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2) 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 upon consideration of all available information. The accuracy of identification is decreased in obese patients.

VI. Comparison of Technological Characteristics with the Predicate Device

The differences and similarities between the above referenced predicate device are listed at a high-level in the following table:

Feature	**Subject Device**	**Predicate Device**
	syngo.CT Dual Energy *(SOMARIS/8 VB60)*	syngo.CT Dual Energy *(SOMARIS/8 VB40, K191468)*
Data Acquisition Mode	The subject device provides post-processing application classes for all four data acquisition modes acquiring images from Dual Source scanners, Dual Energy Single Source, Twin Beam and Photon Counting scanners (PCCT). *Comparison:* The subject device supports newly the post-processing of DICOM image data acquired from Photon Counting scanners. The clinical algorithms of the post-processing application classes remain unchanged.	The subject device provides post-processing application classes for all three data acquisition modes acquiring images from Dual Source scanners, Dual Energy Single Source, and Twin Beam scanners.

While SPP data from Photon-Counting CTs can now be viewed using the general viewing functions and the Virtual Unenhanced and Monoenergetic Plus application classes, the remaining application classes in syngo.CT Dual Energy remain unchanged compared to the predicate version.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

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. The performance data demonstrates continued conformance with special controls for medical devices containing software. The Risk Analysis was completed, and risk control implemented to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation support the claim of substantial equivalence.

Non-Clinical Testing
This submission contains performance tests (Non-clinical test reports) to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT Dual Energy functionality during product development. 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.

Summary of the Evaluation of application classes for Photon Counting Data.

The subject device extends the application classes Monoenergetic Plus and Virtual Unenhanced for Photon Counting Data.

For a technical evaluation, the Multi-Energy CT Phantom (Sun Nuclear Corporation, Melbourne, Florida, USA) was scanned at a NAETOM Alpha (K211591)[1]

For the Monenergetic Plus application class, the calculated values from phantom scans agreed well with the expected ones. Clinical data showed no artifacts. The iodine contrast clearly increased with lower keV settings and decreased with higher ones.

For the Virtual Unenhanced application class it was demonstrated that virtual non-contrast images and iodine concentration can be calculated from spectral data acquired at the NAEOTOM Alpha.

In phantom scans, the measured iodine concentration agrees well with the known iodine concentration. The VNC values are good approximations of the expected water value for all tested iodine concentrations.

In clinical data, the image impression of the virtual non-contrast images was compared with true non-contrast images. Measurements showed good agreement of CT values in the VNCs with the values in the TNCs.

However, it has not been claimed that the VNC can fully substitute a true non-contrast image. In the clinical application of CT imaging, there is always a trade-off between radiation dose and accuracy. Replacing the non-contrast scan with a VNC might save dose, but if the VNC is suitable to answer a specific clinical question cannot be decided here.

Risk Analysis
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.

Siemens hereby certifies that syngo.CT Dual Energy meets the following FDA Recognized Consensus standards listed on the next page:

[1] Display of data specific to new scanners are only applicable after the scanners are commercially available in their own right. This feature is not functional prior to that.

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)/A1:2016	01/14/2019	AAMI, ANSI, IEC
5-125	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Third Edition 2019-12	12/23/2019	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	12/23/2016	IEC
5-117	General I (QS/RM)	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	08/21/2017	ISO

VIII. Conclusion

syngo.CT Dual Energy has the same intended use and same indication for use as the predicate device.

The subject device syngo.CT Dual Energy does not have changes in fundamental scientific technology compared to the predicate devices. The technological characteristics such as image visualization, operating platform, and image measurement are the same as the predicate device.

For the subject device, syngo.CT Dual Energy, Siemens used the same testing with the same workflows as used to clear the predicate device. Siemens considers syngo.CT Dual Energy to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate device.