November 30, 2023

Siemens Medical Solutions, USA, Inc.
℅ Monsuru Bello
Regulatory Affairs Professional
810 Innovation Dr.
KNOXVILLE, TN 37932

Re: K232155
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: October 23, 2023
Received: October 23, 2023

Dear Monsuru Bello:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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)*
K232155

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 1)
- Lung Vessels
- Heart PBV
- Bone Removal
- Lung Perfusion
- Liver VNC 1)
- Monoenergetic Plus 1)
- Virtual Unenhanced 1)
- Bone Marrow
- Hard Plaques
- Rho/Z
- Kidney Stones 1) 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.

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."

510(K) SUMMARY

FOR

SYNGO.CT DUAL ENERGY

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
Siemensstr 1
D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Submitter Contact Person:

Submitter Contact Person:
Monsuru K Bello
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
810 Innovation Drive
Knoxville, TN 37932
Phone: +1 (202) 856-6099
Email: Monsuru.bello@siemens-healthineers.com

Alternate Contact:
Clayton Ginn
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
810 Innovation Drive
Knoxville, TN 37932
Phone: (865) 206-0337
Email: clayton.ginn@siemens-healthineers.com

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

Predicate Device:

Trade Name:	syngo.CT Dual Energy
510(k) Number:	K212889
Clearance Date:	03/28/2022
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Reference Device:

Trade Name:	syngo.CT Extended Functionality
510(k) Number:	K203699
Clearance Date:	04/30/2021
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 VB71 is as follows:

In this software version, additional application classes of syngo.CT Dual Energy can be used with Photon Counting Computed Tomography (PCCT) data. These application classes are Gout Evaluation, Liver VNC and Kidney Stones. There is no change in the algorithm itself, but they support the PCCT acquisition mode only.

In addition, this application uses the feature Lung Lobe Segmentation which supports the automatic segmentation of thoracic images based on lung lobes.

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

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:

- Monoenergetic [1)]
- Brain Hemorrhage
- Gout Evaluation [1)]
- Lung Vessels
- Heart PBV
- Bone Removal
- Lung Perfusion
- Liver VNC [1)]
- Monoenergetic Plus [1)]
- Virtual Unenhanced [1)]
- Bone Marrow
- Hard Plaques
- Rho/Z
- Kidney Stones [1) 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.

VI. Comparison of Technological Characteristics with the Predicate Device

The differences in this software version SOMARIS/8 VB70 are as follows as compared to the predicate device syngo.CT Dual Energy SOMARIS/8 VB60.

1. **Modification: Additional Evaluation of Photon Counting CT Data**
   In this software version SOMARIS/8 VB71, three application classes Gout Evaluation, Liver VNC and Kidney Stones support the evaluation of Photon CT Counting data. The algorithms /functionality of these application classes remain unchanged as compared to the predicate device syngo.CT Dual Energy, SOMARIS/8 VB60 (K212889, clearance date 03/28/2022).

2. **Modification: Lung Lobe Segmentation**
   This application supports the automatic segmentation of thoracic images based on lung lobes. The lung lobe segmentation feature generates mean values and volume for each lung lobe. The resulting data set contains the slices with the segmentation as overlay and a table with the corresponding volumes. This feature is the same as used in the reference device syngo.CT Extended Functionality, SOMARIS/8/ VB51 (K203699, clearance date 04/30/2021).

In this software version, 8 (EIGHT) application classes support the PCCT mode, while in the previous version, 5 classes supported it. For the applications classes Liver VNC, Gout Evaluation and Kidney Stones the algorithms and functionality have not been changed or modified. The core difference is that these classes support the additional fourth acquisition mode (PCCT).

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 Liver VNC, Kidney Stones, and Gout Evaluation to Photon-Counting CT data.

Liver VNC was evaluated on four-phase liver scans from the NAEOTOM Alpha. The virtual non contrast (VNC) images from the three contrast enhanced phases agreed well with the true non contrast images.

The application Kidney Stones was validated on both phantom data and clinical data. In the phantom scans, the size of the stones and the chemical composition computed from PCCT data agreed with the known size and composition of the stones in the phantoms. In clinical data, the performance on PCCT data was similar to the performance on the already approved dual-source dual-energy (DSDE) data.

For Gout, results from PCCT data were directly compared with results from the already approved DSDE scan mode. The volume and the position of Gout tophi were the same for DSDE and PCCT data.

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 below:

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
5-117	General I (QS/RM)	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements 15223-1:2016	8/21/2017	ISO
5-129	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2016+AMD1:2020	07/06/2020	ANSI, AAMI, IEC

Conclusion

syngo.CT Dual Energy has the same intended use and similar 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.