January 3, 2025

Siemens Medical Solutions USA, Inc.
% Kenny M Bello
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE, TN 37932

Re: K241757
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: December 5, 2024
Received: December 5, 2024

Dear Kenny M 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Radiological 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241757

Device Name
sygno.CT Dual Energy

Indications for Use *(Describe)*
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 1)
• Gout Evaluation 1)
• Lung Vessels 1)
• Heart PBV
• Bone Removal
• Lung Perfusion 1)
• Lung Mono 1)
• 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 Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPlus modes.
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 K241757

syngo.CT Dual Energy (VB80)

1. Identification of the Submitter

Submitter / Primary Contact Person	Kenny M Bello Regulatory Affairs monsuru.bello@siemens-healthineers.com +1(202) 856-6099
Secondary Contact Person	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
Submitter Address	Siemens Medical Solutions, Inc. USA Molecular Imaging 810 Innovation Drive Knoxville, TN 37932 Establishment Registration Number: 1034973
Legal Manufacturer	Siemens Healthcare GmbH Siemensstr 1 D-91301 Forchheim, Germany Establishment Registration Number: 3004977335
Importer/Distributor	Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard Malvern, PA 19355 Establishment Registration Number: 2240869

2. 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

3. Predicate Devices

Predicate Device:

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
K-Number:	K232155

4. 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.

The modifications for the software version SOMARIS/8 VB80 are listed in section 7.

5. Indications for Use

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 [1)]
- Gout Evaluation [1)]
- Lung Vessels [1)]
- Heart PBV
- Bone Removal
- Lung Perfusion [1)]
- Lung Mono [1)]
- 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 Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPlus modes.

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.

6. Indications for Use Comparison to the Predicate Device

Subject Device syngo.CT Dual Energy *(SOMARIS/8 VB80)*	**Predicate Device** syngo.CT Dual Energy *(SOMARIS/8 VB71)*
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 [1)]** • Gout Evaluation [1)] • **Lung Vessels [1)]** • Heart PBV • Bone Removal • **Lung Perfusion [1)]** • **Lung Mono [1)]** • 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 Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPlus modes.** 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	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

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

The changes of the IFU-Statement as compared to the predicate device are depicted in bold font. For the changes conducted in SOMARIS/7 VB80, two application classes support Photon-Counting CT scanners: Brain Hemorrhage and Lung Analysis (represented by Lung Vessels and Lung Perfusion). The additional image type called Lung Mono has been included into the IFU statement as well, to reflect the entire functionality of syngo.CT Dual Energy. Furthermore, footnote 1 has been specified to reflect the possibility that some application classes are able to support data from Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPlus modes. The intention of this change is to reflect the distinction between the photon-counter scan-mode "QuantumPlus" and the additional scan-mode called "QuantumPeak".

7. Comparison of Technological Characteristics with the Predicate Device

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

Feature	**Subject Device** **syngo.CT Dual Energy** *(SOMARIS/8 VB80)*	**Predicate Device** **syngo.CT Dual Energy** *(SOMARIS/8 VB71)*
Brain Hemorrhage	The application class visualizes the contrast agent concentration in the case of brain hemorrhage without use of an additional non-contrast scan. Basis for this approach is a material decomposition into contrast agent and soft tissue. The results of this calculation are shown as color overlay to anatomical, grayscale information. This output may be used for complimentary visualization of iodine and overlay maps. **Modification:** Quantum Spectral Imaging (PCCT) scan-mode support.	The application class visualizes the contrast agent concentration in the case of brain hemorrhage without use of an additional non-contrast scan. Basis for this approach is a material decomposition into contrast agent and soft tissue. The results of this calculation are shown as color overlay to anatomical, grayscale information.
Lung Analysis *- Lung Vessels*	This application class visualizes the contrast agent concentration in the lung without use of an additional non-contrast scan. The basis for this approach is a material decomposition into contrast agent and soft tissue. The results of this calculation are shown as color overlay to anatomical, grayscale information. **Modification:** Quantum Spectral Imaging (PCCT) scan-mode support.	This application class visualizes the contrast agent concentration in the lung without use of an additional non-contrast scan. The basis for this approach is a material decomposition into contrast agent and soft tissue. The results of this calculation are shown as color overlay to anatomical, grayscale information.

Feature	Subject Device **syngo.CT Dual Energy** *(SOMARIS/8 VB80)*	Predicate Device **syngo.CT Dual Energy** *(SOMARIS/8 VB71)*
- Lung Perfusion	The application class visualizes the contrast agent concentration in the lung without use of an additional non-contrast scan. The basis for this approach is a material decomposition into contrast agent and soft tissue. The results of this calculation are shown as color overlay to anatomical, grayscale information. An optional lung isolation is provided. Lung Mono series should not be interpreted in isolation. **Modification:** Quantum Spectral Imaging (PCCT) scan-mode support for Lung PBV. Availability of an additional image type (Lung Mono) for dual source dual energy and Quantum Spectral Imaging (PCCT) scan modes.	The application class visualizes the contrast agent concentration in the lung without use of an additional non-contrast scan. The basis for this approach is a material decomposition into contrast agent and soft tissue. The results of this calculation are shown as color overlay to anatomical, grayscale information. An optional lung isolation is provided.
Monoenergetic Plus	This application class simulates images that are equivalent to images scanned with a single photon energy beam, depending on the energy (keV). **Modification:** Dual Source Dual Energy (DSDE) data from PCCT (QuantumPeak) can be loaded.	This application class simulates images that are equivalent to images scanned with a single photon energy beam, depending on the energy (keV).
Bone Marrow	This application class allows to visualize the bone marrow composition based on nonenhanced CT data. It generates virtual non-calcium (VNCa) images by subtracting calcium from the Dual Energy data sets. **Modification:** Dual Source Dual Energy (DSDE) data from PCCT (QuantumPeak) can be loaded.	This application class allows to visualize the bone marrow composition based on nonenhanced CT data. It generates virtual non-calcium (VNCa) images by subtracting calcium from the Dual Energy data sets.
Kidney Stones	This application class visualizes the chemical differences between kidney stones by decomposing the kidney stones into its component parts: tissue, uric acid, and oxalate (calcium stone). **Modification:** Dual Source Dual Energy (DSDE) data from PCCT (QuantumPeak) can be loaded.	This application class visualizes the chemical differences between kidney stones by decomposing the kidney stones into its component parts: tissue, uric acid, and oxalate (calcium stone).
Virtual Unenhanced	This application class visualizes the contrast agent concentration in soft body tissue without the need of an additional non-contrast scan. **Modification:** Dual Spiral/Twin Spiral scan-mode support for Virtual Unenhanced.	This application class visualizes the contrast agent concentration in soft body tissue without the need of an additional non-contrast scan.

The remaining applications classes/functions in syngo.CT Dual Energy remain unchanged compared to the predicate version:

- SPR (Stopping Power Ratio)
- SPP (Spectral Post-Processing Format)
- Monoenergetic
- Gout Evaluation
- Bone Removal
- Hard Plaques
- Rho/Z
- Lung Lobe Segmentation

8. Performance Data

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

Software Verification and Validation

Software Documentation for Enhanced documentation Level per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, is also included as part of this submission. 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.

Summary of Performance Testing

DE Brain Hemorrhage for Photon-Counting CT

We performed a two-reader study to assess the clinical performance of the application class DE Brain Hemorrhage on photon-counting CT (PCCT) data, comparing the reading results on VNC and Iodine images with later follow-up data. The study demonstrated that DE Brain Hemorrhage can provide complementary visualization of iodine and overlay maps as demonstrated in a two reader study where 24 of 28 features were identified by both readers. Of all 28 features, 19 were assessed to be pure hemorrhage, 6 to be pure iodine staining, and 3 to be a mix of both, hemorrhage and iodine.

Lung Mono for Dual Source Dual Energy

A two-reader study on twenty cases of suspected pulmonary embolisms was performed. The test demonstrated adequate agreement between the position of obstructing clots and the location of perfusion defects in the Lung Mono maps. Thus, the Lung Mono maps can provide complementary visualization for the purposes of identifying and locating perfusion defects caused by obstructing clots. *Lung Mono images should not be interpreted alone.*

Lung Analysis (Lung PBV, Lung Mono, and Lung Vessels) for Photon-Counting CT

A two-reader study on 33 cases of suspected pulmonary embolisms was performed to assess the performance of Lung PBV, Lung Mono, and Lung Vessel maps.

The test demonstrated that the three image types visualize reduced local iodine content, either in the lung parenchyma or in the lung arteries. The test was based on obstructing clots, which are the cause of pulmonary embolism and can be identified in conventional CT images by trained radiologists.

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:

Standard	Version	Content	FDA Recognition Number (if applicable)
ANSI AAMI IEC 62304	:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	13-79
NEMA PS 3.1 - 3.20 2022d	:2022	Digital Imaging and Communications in Medicine (DICOM) Set	12-349
ISO 14971	:2019	Application of Risk Management to Medical Devices	5-125
IEC 62366-1	Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices	5-129
ISO 15223-1	Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5-134
ISO 20417:2021	First edition 2021-04 Corrected version 2021-12	Medical devices - Information to be supplied by the manufacturer	5-135

9. 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.