U.S. FOOD & DRUG ADMINISTRATION

October 15, 2025

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

Re: K251805
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: August 8, 2025
Received: September 12, 2025

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 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251805

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:
• Bone Marrow 2)
• Bone Removal 1)
• Brain Hemorrhage 1)
• Gout Evaluation 1)
• Hard Plaques 1)
• Heart PBV
• Kidney Stones 1) 2) 3)
• Liver VNC 1)
• Lung Mono 1)
• Lung Perfusion 1)
• Lung Vessels 1)
• Monoenergetic 1) 2)
• Monoenergetic Plus 1) 2)
• Optimum Contrast 1) 2)
• Rho/Z 1) 2)
• SPP (Spectral Post-Processing Format) 1) 2)
• SPR (Stopping Power Ratio) 1) 2)
• Virtual Non-Calcium (VNCa) 1) 2)
• Virtual Unenhanced 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) This functionality supports data from Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPeak modes.

3) 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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K251805 - 510(k) Summary

syngo.CT Dual Energy (VC10)

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:	K241757

Reference Device:

Trade Name:	*syngo.*via RT Image Suite
Classification Name:	Medical charged-particle radiation therapy system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.5050
Device Class:	Class II
Product Code:	MUJ
K-Number:	K232799

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 product is intended to be used for at least 21-year-old humans.

5. 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:

- Bone Marrow[2)]
- Bone Removal[1)]
- Brain Hemorrhage[1)]
- Gout Evaluation[1)]
- Hard Plaques[1)]
- Heart PBV
- Kidney Stones[1) 2) 3)]
- Liver VNC[1)]
- Lung Mono[1)]
- Lung Perfusion[1)]
- Lung Vessels[1)]
- Monoenergetic[1) 2)]
- Monoenergetic Plus[1) 2)]
- Optimum Contrast[1) 2)]
- Rho/Z[1) 2)]
- SPP (Spectral Post-Processing Format)[1) 2)]

- SPR (Stopping Power Ratio)1) 2)
- Virtual Non-Calcium (VNCa)1) 2)
- Virtual Unenhanced1)

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) This functionality supports data from Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPeak modes.
3) 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 VC10)*	**Predicate Device** syngo.CT Dual Energy *(SOMARIS/8 VB80)*
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: • Bone Marrow2) • **Bone Removal1)** • Brain Hemorrhage1) • Gout Evaluation1) • **Hard Plaques1)** • Heart PBV • Kidney Stones1) 2) 3) • Liver VNC1) • Lung Mono1) • Lung Perfusion1) • Lung Vessels1) • Monoenergetic1) 2) • Monoenergetic Plus1) 2) • Optimum Contrast1) 2) • **Rho/Z1) 2)**	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 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

• SPP (Spectral Post-Processing Format)1) 2) **• SPR (Stopping Power Ratio)1) 2)** **• Virtual Non-Calcium (VNCa)1) 2)** • Virtual Unenhanced1) 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) This functionality supports data from Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPeak modes.** 3) 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.	• 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.

The changes of the IFU-Statement as compared to the predicate device are depicted in bold font.

- For the changes conducted in SOMARIS/8 VC10, five application classes support Photon-Counting CT scanners: Bone Removal, Hard Plaques, SPR, Rho/Z and Virtual Non-Calcium (VCNa)
- The following classes support in SOMARIS/8 VC10 the QuantumPeak scan-mode: SPR, Rho/Z and Virtual Non-Calcium (VCNa)
- Comparing both IFU-Statements, an additional footnote has been incorporated in order document which application classes support the QuantumPeak scan-mode. The footnote is as follows: "*2) This functionality supports data from Siemens Healthineers Photon-Counting CT scanners acquired in QuantumPeak modes.*"

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:

Extensions of the subject device	Subject Device	Predicate Device
	syngo.CT Dual Energy *(SOMARIS/8 VC10)*	syngo.CT Dual Energy *(SOMARIS/8 VB80)*
SPR (Stopping Power Ratio)	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. **Modification:** Quantum Spectral Imaging (PCCT) and QuantumPeak scan-mode support.	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.
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. **Modification:** Warning about non-quantitative use of Quantum Spectral Imaging Scans (PCCT) has been removed.	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 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. **Modification:** Warning about non-quantitative use of Quantum Spectral Imaging Scans (PCCT) has been removed.	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.
Bone Removal	This application class removes bone or dense plastic from CT angiography (CTA) data sets. The prerequisite for a bone removal is the decomposition of the material into its component parts: blood, contrast agent, and bone. **Modification:** Quantum Spectral Imaging (PCCT) scan-mode support.	This application class removes bone or dense plastic from CT angiography (CTA) data sets. The prerequisite for a bone removal is the decomposition of the material into its component parts: blood, contrast agent, and bone.

Extensions of the subject device	Subject Device	Predicate Device
	syngo.CT Dual Energy *(SOMARIS/8 VC10)*	syngo.CT Dual Energy *(SOMARIS/8 VB80)*
Liver VNC	The Liver VNC application class allows to visualize the contrast agent concentration in the liver without an additional non-contrast scan, even if there are irregular fatty infiltrations or necrotic areas. The application class generates virtual non-contrast (VNC) images by subtracting iodine from the Dual Energy data sets. The VNC images can be used for baseline density measurements. In addition, this application class provides fat map evaluation for contrast enhanced CT-scans as well as for non-contrast scans. **Modification:** • Fat Map for Quantum Spectral Imaging Scans (PCCT) • Support of normalized iodine maps called Extracellular Volume (ECV)	The Liver VNC application class allows to visualize the contrast agent concentration in the liver without an additional non-contrast scan, even if there are irregular fatty infiltrations or necrotic areas. The application class generates virtual non-contrast (VNC) images by subtracting iodine from the Dual Energy data sets. The VNC images can be used for baseline density measurements. In addition, this application class provides fat map evaluation for contrast enhanced CT-scans as well as for non-contrast scans.
Hard Plaques	This application class highlights calcified plaques within large vessels even if they have CT values that are comparable to the neighboring contrast medium. **Modification:** Quantum Spectral Imaging (PCCT) scan-mode support.	This application class highlights calcified plaques within large vessels even if they have CT values that are comparable to the neighboring contrast medium.
Rho/Z	This application class measures electron density as well as effective atomic number and performs a basic characterization of the material of interest. **Modification:** Quantum Spectral Imaging (PCCT) and QuantumPeak scan-mode support.	This application class measures electron density as well as effective atomic number and performs a basic characterization of the material of interest.

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

- SPP (Spectral Post-Processing Format)
- Monoenergetic
- Gout Evaluation
- Lung Analysis (Lung Vessels, Lung Mono)
- Heart PBV
- Monoenergetic Plus
- Virtual Unenhanced
- Kidney Stones
- 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

Liver VNC – Fat Map for Photon-Counting CT

The feature Liver VNC – Fat Map was tested on clinical PCCT scans with contrast enhancement, comparing the results against fat values calculated from non-contrast CT scans. The limits of agreement (LoAs) between both methods were [-8.6%, -1.0%] with a mean deviation of -3.8%. Thus, the feature Fat Map overestimates the reference value on average, but the LoAs remain within the prescribed tolerance of +/- 10%.

Together with the supporting literature it is concluded that the feature is safe and effective.

Liver VNC – Extracellular Volume Maps for Photon-Counting CT

The software was validated on phantom data. The test results show that the implementation of ECV maps in syngo.CT Dual Energy is accurate up to an absolute error of 2% ECV, even in the presence of fat in the liver parenchyma.

The ECV was compared against ultrasound derived shear-wave elastography (US-SWE) in 25 clinical cases. A statistical relevant rank correlation between hepatic ECV values and US-SWE was found.

A literature review showed that CT-derived ECV is well investigated and might be useful for the assessment of fibrosis and cirrhosis in the liver.

On conclusion, the device is safe to compute ECV maps from PCCT scans in the equilibrium phase and the ECV value is clinically useful.

Bone Removal for Photon-Counting CT

The clinical performance of the application class DE Body Bone Removal applied to PCCT data was evaluated with a three-reader study. The readers assessed the quality of the bone removal by means of residual bone and its impact on the image interpretability. The bone removal was rated to be of sufficient quality with no residual bone interfering with image interpretation in over 90% of the ratings. Additionally, the performance regarding the visualization of vessels by means of artifacts induced by the application was assessed. Each reader evaluated over 90% of the cases to be free of major artifacts in vessels.

The clinical performance of the application class DE Head Bone Removal on PCCT data was evaluated with a three-reader study. The readers assessed the quality of the bone removal by means of residual bone and its impact on the image interpretability. The bone removal was concordantly rated to be sufficient with residual bone that interferes with image interpretation in less than 2% of the ratings. Additionally, the performance regarding the visualization of vessels by means of artifacts induced by the application was assessed. Major artifacts were found predominantly for the vertebral arteries and parts of the internal carotid arteries. Thus, applying the DE Head Bone Removal application class to PCCT data may provide limited result quality for vertebral arteries, and segments of the internal carotid arteries close to the carotid canal. This limitation is pointed out in the Instructions for Use.

Hard Plaques for Photon-Counting CT

The clinical performance of the application class DE Hard Plaques applied to PCCT data was evaluated with a three-reader study. The readers assessed the labelling of hard plaques in the abdominal aorta and iliac arteries by means of true positive and false positive labelling in combination with its clinical implicated type of stenosis. The DE Hard Plaques application class labels most of the relevant plaques in above 85% of the ratings. No case of global failure was present. Furthermore, false positive labelling was found in less than 20% of the ratings. The most severe stenosis implied was moderate in less than 10% of the cases in which false positives labelling occurred. Otherwise, no or mild stenosis was implied.

VNCa for Photon-Counting CT

A phantom with inserts mimicking red and yellow bone marrow combined with several concentrations of hydroxyapatite (HA) was scanned with photon-counting CT. The test demonstrated that the calcium signal is removed from the material inserts containing HA. Although over-subtraction was noted, the relative contrast between yellow and red marrow at the same HA concentration was retained in the VNCa maps.

Rho/Z/SPR for Photon-Counting CT

The tests are based on two phantoms with sizes comparable to a human head and a human abdomen. The phantoms were equipped with inserts of known material composition. Measurements were performed in clinically relevant routine protocols at typical dose levels.

The material parameters relative electron density (RED, Rho) and effective atomic number (EAN, Z) were automatically derived with the application syngo.CT DE Rho/Z and provided a basic characterization of the materials of interest. This was demonstrated with tissue-equivalent materials covering a wide range of human tissues (lung, adipose, soft tissue, bone). Furthermore, the test demonstrated that the derived RED values were within ± 3% (with respect to water) and EAN values were within ± 1.

The material parameter stopping power ratio (SPR) was automatically derived with the application syngo.CT DE SPR and provided the stopping-power ratio of a material of interest at a proton energy of 100 MeV. This was demonstrated with tissue-equivalent materials covering a wide range of human tissues (lung, adipose, soft tissue, bone). Furthermore, the test demonstrated that the derived SPR values were within ± 3% with respect to water.

Brain Hemorrhage and Lung PBV – Quantitative Use with Photon-Counting CT

The quantitative performance of virtual-non contrast (VNC) and iodine material density (IMD) maps computed by DE Brain Hemorrhage was compared between dual-source dual energy (DSDE) and photon-counting CT (PCCT) data. The clinically relevant situation was simulated by a phantom of 20 cm diameter and six material inserts with varying iodine concentration and blood density.

The IMD measurements deviated by -0.2 mg I / ml to 0.3 mg I / ml from the nominal values of the material inserts with no systematic difference between DSDE and PCCT scans. The VNC values showed small variations across the scan modes in the order of 10 HU. Increased blood density resulted in substantially increased VNC values, while iodine enhancement was clearly removed.

In summary, the virtual non-contrast and iodine material density maps created from photon-counting CT scans show a similar accuracy as the maps created from Dual Source Dual Energy scans.

The quantitative performance of Lung PBV computed by DE Lung Analysis was compared between dual-source dual energy (DSDE) and photon-counting CT (PCCT) data for different scan modes. The clinically relevant situation was simulated by a phantom of 20 cm diameter and different material inserts mimicking lung tissue with iodine. Additionally, iodine in water at different iodine concentrations were tested.

The maximum absolute deviation from PCCT data is generally lower compared to the one from DSDE for all iodine in water inserts as well as most of the lung tissue and iodine inserts. Exceptions are the lung tissue with 0.0 mg/ml and 1.0 mg/ml iodine concentration, for the which the deviations from one PCCT mode were slightly higher, but still comparable to the one from DSDE data.

In summary, the iodine enhancement provided by Lung PBV as part of DE Lung Analysis derived from PCCT scans show a comparable accuracy as the one from DSDE scans.

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 2023e	:2022	Digital Imaging and Communications in Medicine (DICOM) Set	12-352
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

Standard	Version	Content	FDA Recognition Number (if applicable)
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.