March 7, 2022

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

Re: K220450
Trade/Device Name: syngo.CT Applications
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: February 15, 2022
Received: February 17, 2022

Dear Mr. 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.
Assistant Director
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)*

K220450

Device Name
syngo.CT Applications

Indications for Use *(Describe)*

syngo.CT Applications is a set of software applications for advanced visualization, measurement, and evaluation for specific body regions.

This software package is designed to support the radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice e.g. in the:

- Evaluation of perfusion of organs and tumors and myocardial tissue perfusion
- Evaluation of bone structures and detection of bone lesions
- Evaluation of CT images of the heart
- Evaluation of the coronary lesions
- Evaluation of the mandible and maxilla
- Evaluation of dynamic vessels and extended phase handling
- Evaluation of the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver
- Evaluation of neurovascular structures
- Evaluation of the lung parenchyma
- Evaluation of non-enhanced Head CT images
- Evaluation of vascular lesions

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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K220450

510(k) Summary

I. Identification of the Submitter

Importer/Distributor
Siemens Medical Solutions USA, Inc.
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Malvern, PA 19355

Establishment Registration Number
2240869

Manufacturing Site
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Establishment Registration Number
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II. Device Name and Classification

Product Name:	syngo.CT Applications
Propriety Trade Name:	syngo.CT Applications
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

Primary Predicate:

Trade Name:	syngo.CT Pulmo 3D

510(k) Number: K123540
Clearance Date: 08/29/2013
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

Reference Predicates:

Trade Name: syngo.CT Body Perfusion
510(k) Number: K092013
Clearance Date: 07/17/2009
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

Trade Name: syngo.CT Bone Reading
510(k) Number: K123584
Clearance Date: 03/12/2013
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

Trade Name: syngo.CT Cardiac Function
510(k) Number: K123585
Clearance Date: 12/20/2012
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

Trade Name: syngo.CT Coronary Analysis
510(k) Number: K173637
Clearance Date: 03/30/2018
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

Trade Name: syngo.CT Dental
510(k) Number: K150785

Clearance Date:	05/18/2015
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Trade Name:	syngo.CT Dynamic Angio
510(k) Number:	K120331
Clearance Date:	04/13/2012
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Trade Name:	syngo.CT Liver Analysis
510(k) Number:	K133643
Clearance Date:	11/13/2014
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Trade Name:	syngo.CT Myocardial Perfusion
510(k) Number:	K150713
Clearance Date:	11/02/2015
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Trade Name:	syngo.CT Neuro DSA
510(k) Number:	K053024
Clearance Date:	11/04/2005
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Trade Name:	syngo.CT Neuro Perfusion
510(k) Number:	K202213
Clearance Date:	10/11/2020
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology

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

Trade Name:	syngo.CT Skull Unfolding
510(k) Number:	K203411
Clearance Date:	07/22/2021
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Trade Name:	syngo.CT Vascular Analysis
510(k) Number:	K173637
Clearance Date:	03/30/2018
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

The syngo.CT Applications are syngo based post-processing software applications to be used for viewing and evaluating CT images provided by a CT diagnostic device and enabling structured evaluation of CT images.

The syngo.CT Applications is a combination of thirteen (13) former separately cleared medical devices which are now handled as features / functionalities within syngo.CT Applications. These functionalities are combined unchanged compared to their former cleared descriptions; however, some minor enhancements and improvements are made for the application syngo.CT Pulmo 3D only.

The table below shows the functionalities of syngo.CT Applications:

Single Application	**Functionality and description**
syngo.CT Body Perfusion	• Evaluation of perfusion of organs and tumors. • Calculation blood flow, blood volume and permeability from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media • Separate calculation of arterial and portal venous component of hepatic perfusion • Evaluation of regions of interest and visual inspection of time density curves • Deconvolution methods
syngo.CT Bone Reading	• visualizations of spine and rib structures • multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT) • geometric measurement tools (distance line, polyline, marker, arrow, angle) • HU measurement tools (Pixel lens, ROI circle, ROI polygonal, ROI freehand, VOI sphere) • curved MPR visualization (unfolded ribs and spine views), crosssection MPRs • tools for creation and editing of anatomical centerline paths • tools for creation and editing of anatomical labels

Single Application	Functionality and description
syngo.CT Cardiac Function	• Evaluation of CT images of the heart. • Digital image processing and visualization tools (2D, 3D and 4D display of dynamic data), • Evaluation tools (structural and functional analysis of heart chambers and valves, and analysis of myocardial tissue) • Reporting tools
syngo.CT Coronary Analysis	• Evaluating of cardiac CT angiography (CTA) volume data sets • Combination of digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)) • Evaluation tools (coronary vessel centerline calculation, stenosis calculation and plaque analysis) and reporting tools (lesion location, lesion characteristics and key images), • Designed to support the physician in confirming the presence or absence of physician-identified coronary lesions and evaluation, documentation and follow-up of any such lesion These visualization/evaluation tools allow for characterization (geometry (length, lumen diameter, cross section area, stenos is grade) and appearance (HU values)) of coronary lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.
syngo.CT Dental	• Basic reading tools (multiplanar reconstruction (MPR), maximum intensity projection (MIP), volume rendering technique (VRT), minimal intensity projection (MinIP) • Basic geometric measurement tools (distance line, polyline, marker, arrow, angle) • Basic HU measurement tools (Pixel lens, ROI Circle, ROI polygonal, ROI freehand, VOI sphere, VOI freehand) • Dedicated dental visualization tools (Dental panoramic views (curved MPRs) and dental paraxial views (cross-section MPRs) that are calculated based on a manually defined centerline) • Tool to manually outline the mandibular canal • Tool that allows paraxial and panoramic result images to be saved as dental range series. • True Size (1:1) printing of panoramic and paraxial images to allow anatomy to be printed in its actual size on the film sheet.
syngo.CT Dynamic Angio	• Visualization of flow of contrast from the arteries to the veins with contrast enhanced CT images • Supports in the evaluation of regions of interest, the visual inspection of time attenuation curves, and the creation of specific CT volumes, for example, arterial or venous phase.
syngo.CT Liver Analysis	• Evaluation of the liver volume and examination of the vessels of the liver • Computation and manual correction of liver volumes • Computation and manual correction of tumor volumes and extent • Computation and manual correction of liver vessel tree structure • Computation of territories based on vessel branches • Tumor position in relation to vessels (i.e., 3D visualization of liver, tumor, and vessels) • Manual definition of separation plane proposals • Computation of volume of liver parts • Combination of information from different CT and MR phase volumes
syngo.CT Myocard Perfusion	• Evaluation of the perfusion of the myocardium • Calculation of blood flow, blood volume, and other hemodynamic parameters from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media • Evaluation of regions of interest and the visual inspection of time attenuation curves
syngo.CT Neuro DSA	• Removing of bone structures from CT Angiography (CTA) data sets of the cerebral vasculature • Bone removal is based on a bone mask created from an additional non enhanced CT (NECT) scan that was three-dimensionally registered to the CTA data set

Single Application	Functionality and description
syngo.CT Neuro Perfusion	• The syngo.CT Neuro Perfusion software package is designed to evaluate areas of brain perfusion. The software processes images or volumes that were reconstructed from continuously acquired CT data after the injection of contrast media. • Generation of the following result volumes: Cerebral blood flow (CBF), Cerebral blood volume (CBV), Local bolus timing (time to start (TTS), time to peak (TTP), time to drain (TTD)), Mean transit time (MTT), Transit time to the center of the IRF (TMax), Flow extraction product (permeability), Temporal MIP, Temporal Average, Baseline Volume , Modified dynamic input data • The software allows the calculation of mirrored regions of interest and the visual inspection of time attenuation curves. • One clinical application is to visualize the apparent blood perfusion and to calculate Hypoperfused Area and Mismatch Ratio in the brain tissue affected by acute stroke. • Areas of decreased perfusion appear as areas of changed signal intensity: Lower signal, intensity for CBF and CBV, Higher signal intensity for TTP, TTD, MTT, and TMax • A second application is to visualize blood brain barrier disturbances by modeling extra-vascular leakage of blood into the interstitial space. This additional capability may improve the differential diagnosis of brain tumors and may be helpful in therapy monitoring.
syngo.CT Pulmo 3D	• syngo.CT Pulmo 3D analyses the lung, either completely or in parts, identifying areas with lower or higher Hounsfield values in comparison to a predefined threshold. These areas are evaluated using statistical methods such as histograms and percentiles. • Examination of the lung parenchyma and the airways of the lung • Evaluation Tools (computation of lung volumes, display of statistics related to the lung, setting of markers, airway measurements)
syngo.CT Skull Unfolding	• This software provides advanced visualization of the skull and brain surface for easy manual identification, marking and reporting of pathologies such as skull fractures and hematomas.
syngo.CT Vascular Analysis	• syngo.CT Vascular Analysis is an image analysis software package for evaluating enhanced CT images. • Visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) • Evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) • Reporting tools (lesion location, lesion characteristics and key images), • the software package is designed to support the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such lesion. These visualization/processing/evaluation tools allow for characterization (geometry (length, lumen diameter, cross section area, stenosis grade) and appearance (HU values)) of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

The Appendix D – Revision Level History outlines the clearance dates for all applications and all modifications/bug fixes completed in each release of the devices since. These changes did not constitute the need for a 510(k) according to "Deciding When to Submit a 510(k) for a Software Change to an Existing Device", October 25, 2017. (i.e. these modifications did not change the indication for use or safety or effectiveness, change clinical functionality or performance specifications, or introduce new risks or necessitate new risk control measures.)

Except for the new product composition, the only change with this release includes some minor improvements and enhancements of the existing functionalities within the syngo.CT Pulmo 3D application:

For verification purposes, syngo.CT Pulmo 3D in the software version SOMARIS/8 VB70 provides an assignment of different colors to the lobe borders in the lobe visualization. In this software version,

the same colors are used which were previously provided to the end-user as table headings for each lobe in the previous version. The colors are as follows:

- Upper Left Lobe: orange
- Lower Left Lobe: pink
- Upper Right Lobe: yellow
- Middle Right Lobe: green
- Lower Right Lobe: light blue

This coloring will be disabled as soon as one of the analysis modes is activated to avoid confusion with the colors used for the various analyzes of the lung parenchyma.

V. Indications for Use

syngo.CT Applications is a set of software applications for advanced visualization, measurement, and evaluation for specific body regions.

This software package is designed to support the radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice e.g. in the:

- Evaluation of perfusion of organs and tumors and myocardial tissue perfusion
- Evaluation of bone structures and detection of bone lesions
- Evaluation of CT images of the heart
- Evaluation of the coronary lesions
- Evaluation of the mandible and maxilla
- Evaluation of dynamic vessels and extended phase handling
- Evaluation of the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver
- Evaluation of neurovascular structures
- Evaluation of the lung parenchyma
- Evaluation of non-enhanced Head CT images
- Evaluation of vascular lesions

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device is a combination of the thirteen (13) former separate medical devices. The main functionalities of the predicate devices are used unchanged for syngo.CT Applications SOMARIS/VB70 except the minor changes within syngo.CT Pulmo 3D.

Subject Device	**Predicate Device Information**			
Application within the bundle device syngo.CT Applications	**Product Name**	**Product Code**	**K-Number**	**Clearance Date**
syngo.CT Body Perfusion	syngo.CT Body Perfusion	JAK	K092013	07/17/2009
syngo.CT Bone Reading	syngo.CT Bone Reading	JAK	K123584	03/12/2013
syngo.CT Cardiac Function	syngo.CT Cardiac Function	JAK	K123585	12/20/2012
syngo.CT Coronary Analysis	syngo.CT Coronary Analysis	JAK	K173637	03/30/2018
syngo.CT Dynamic Angio	syngo.CT Dynamic Angio	JAK	K120331	04/13/2012
syngo.CT Dental	syngo.CT Dental	JAK	K150785	05/18/2015

Subject Device	Predicate Device Information			
Application within the bundle device syngo.CT Applications	**Product Name**	**Product Code**	**K-Number**	**Clearance Date**
syngo.CT Liver Analysis	syngo.CT Liver Analysis	JAK	K133643	11/13/2014
syngo.CT Myocardial Perfusion	syngo.CT Myocardial Perfusion	JAK	K150713	11/02/2015
syngo.CT Neuro DSA	syngo.CT Neuro DSA	JAK	K053024	11/04/2005
syngo.CT Neuro Perfusion	syngo.CT Neuro Perfusion	JAK	K202213	10/11/2020
syngo.CT Pulmo 3D	syngo.CT Pulmo 3D	JAK	K123540	08/29/2013
syngo.CT Skull Unfolding	syngo.CT Skull Unfolding	JAK	K203411	07/22/2021
syngo.CT Vascular Analysis	syngo.CT Vascular Analysis	JAK	K173637	03/30/2018

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.

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	12/23/2016	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	AAMI, ANSI, IEC

5-117	General (QS/RM)	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements ISO 15223-1 Third Edition 2016-11-01	08/21/2017	ISO

VIII. Conclusion

The syngo.CT Applications are intended for similar indications as cleared in their according predicate devices.

Since the thirteen (13) formerly cleared separate medical devices have been consolidated into one (1) medical device, the Indications for Use has been updated. However, the newly revised indication for use does not introduce any new specific clinical indications/features. The intended use of the former devices remains unchanged. The fundamental scientific technology and technological characteristics are the same as the predicate devices.

The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The comparison of technological characteristics and software validation demonstrates that the subject device is as safe and effective when compared to the predicate device that is currently marketed for the same intended use.

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

Therefore, Siemens believes that the subject device, the syngo.CT Applications does not raise new questions of safety and effectiveness and is substantially equivalent to their primary predicate devices listed above in Table 1.