



January 4, 2024

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

Re: K232136
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: December 13, 2023
Received: December 13, 2023

Dear Clayton Ginn:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,

Gabriela M. Rodal -S Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.

Assistant Director

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

Indications for Use

510(k) Number (if known)
K232136

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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510(k) Summary – K232136

1. Identification of the Submitter

Submitter / Primary Contact Person	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
Secondary Contact Person	Monsuru (Kenny) Bello Regulatory Affairs monsuru.bello@siemens-healthineers.com +1 (240) 601-3848
Submitter Address	Siemens Medical Solutions, Inc. USA Molecular Imaging 810 Innovation Drive Knoxville, TN 37932 Establishment Registration Number: 1034973
Manufacturing Site	Siemens Healthcare GmbH Siemensstr 1 -or- Rittigfeld Forchheim, Bavaria, DE 91301 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 Applications
 Propriety Trade Name: *syngo*.CT Applications
 Regulation Name: Computed tomography x-ray system
 Classification Name: System, X-ray, Tomography, Computed
 Classification Panel: Radiology
 CFR Section: 21 CFR §892.1750
 Device Class: Class II
 Product Code: JAK

3. Predicate Devices

Primary Predicate Device:

Trade Name: *syngo*.CT Applications
 510(k) Number: K220450
 Clearance Date: 03/07/2022
 Regulation Name: Computed tomography x-ray system
 Classification Name: System, X-ray, Tomography, Computed
 Classification Panel: Radiology

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

Reference Devices

Trade Name: *syngo*.CT CaScoring
 510(k) Number: K221219
 Clearance Date: 05/17/2022
 Regulation Name: Computed tomography x-ray system
 Classification Name: System, X-ray, Tomography, Computed
 Classification Panel: Radiology
 CFR Section: 21 CFR §892.1750
 Device Class: Class II
 Product Code: JAK

Trade Name: *syngo*.CT Extended Functionality
 510(k) Number: K203699
 Clearance Date: 04/30/2021
 Regulation Name: Computed tomography x-ray system
 Classification Name: System, X-ray, Tomography, Computed
 Classification Panel: Radiology
 CFR Section: 21 CFR §892.1750
 Device Class: Class II
 Product Code: JAK

4. 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 fourteen (14) medical devices which are handled as features / functionalities within *syngo*.CT Applications.

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

Single Application	Functionality and description
<i>syngo</i> .CT Body Perfusion	<ul style="list-style-type: none"> • 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

Single Application	Functionality and description
syngo.CT Bone Reading	<ul style="list-style-type: none"> • 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), crossection MPRs • tools for creation and editing of anatomical centerline paths • tools for creation and editing of anatomical labels
syngo.CT Cardiac Function	<ul style="list-style-type: none"> • 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 CaScoring	<ul style="list-style-type: none"> • Loading of a series of appropriate CT- or MR-Images from the patient database • Browsing, selecting, and displaying images for searching calcium regions/lesions • Interactive definition of ROIs and assignment of the four major coronary arteries (LM, LAD, CX and RCA) to the lesions • Calculation and display of the 2D-Agatston score/factor or other metric on the defined ROIs • Interactive definition of ROIs (for example noise) to disqualify the region from participation in the score • Displaying the score in form of result tables/reports on paper and/or film • Pan and Zoom functionality/windowing • Reformatting • Comparison of score to cited literature
syngo.CT Coronary Analysis	<ul style="list-style-type: none"> • 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, stenosis 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.

Single Application	Functionality and description
syngo.CT Dental	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

This subject device which is versioned as SOMARIS/8 VB80 includes the following types of changes:

- *syngo*.CT CaScoring – Added to the subject device as a fourteenth application and extended the export function to include a DICOM Structured Report.
- *syngo*.CT Pulmo 3D – Added an interface to *syngo*.CT Lung CAD (latest clearance: K203258, K231157), and integrated the lung lobe segmentation algorithm from *syngo*.CT Extended Functionality (K203699).

5. 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

6. Indications for Use Comparison to the Predicate Device

There is no change to the indications for use. Each bulleted function in the indications for use relates to one of the now bundled applications. The new application *syngo*.CT CaScoring falls under the phrase ‘Evaluation of coronary lesions’.

Function	Related Application
Evaluation of perfusion of organs and tumors and myocardial tissue perfusion	<i>syngo</i> .CT Body Perfusion <i>syngo</i> .CT Myocardial Perfusion
Evaluation of bone structures and detection of bone lesions	<i>syngo</i> .CT Bone Reading <i>syngo</i> .CT Skull Unfolding
Evaluation of CT images of the heart	<i>syngo</i> .CT Cardiac Function
Evaluation of the coronary lesions	<i>syngo</i> .CT Coronary Analysis <i>syngo</i> .CT CaScoring
Evaluation of the mandible and maxilla	<i>syngo</i> .CT Dental
Evaluation of dynamic vessels and extended phase handling	<i>syngo</i> .CT Dynamic Angio
Evaluation of the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver	<i>syngo</i> .CT Liver Analysis

Evaluation of neurovascular structures	<i>syngo</i> .CT Neuro Perfusion
Evaluation of the lung parenchyma	<i>syngo</i> .CT Pulmo 3D
Evaluation of non-enhanced Head CT images	<i>syngo</i> .CT Neuro DSA
Evaluation of vascular lesions	<i>syngo</i> .CT Vascular Analysis

7. Comparison of Technological Characteristics with the Predicate Device

The subject device is a combination of the fourteen (14) medical devices. The main functionalities of the predicate device is unchanged for *syngo*.CT Applications SOMARIS/VB70 except the minor changes within *syngo*.CT Pulmo 3D. For this subject device, the legally marketed *syngo*.CT CaScoring application was bundled to the subject device and the export function was extended.

Subject Device <i>syngo</i> .CT Applications (SOMARIS/8 VB80)	Predicate Device <i>syngo</i> .CT Applications (SOMARIS/8 VB70)	Comparison Result
Built-in applications in the subject device “<i>syngo</i>.CT Applications”		
<i>syngo</i> .CT Body Perfusion	<i>syngo</i> .CT Body Perfusion	Same
<i>syngo</i> .CT Bone Reading	<i>syngo</i> .CT Bone Reading	Same
<i>syngo</i> .CT Cardiac Function	<i>syngo</i> .CT Cardiac Function	Same
<i>syngo</i> .CT Coronary Analysis	<i>syngo</i> .CT Coronary Analysis	Same
<i>syngo</i> .CT Dynamic Angio	<i>syngo</i> .CT Dynamic Angio	Same
<i>syngo</i> .CT Dental	<i>syngo</i> .CT Dental	Same
<i>syngo</i> .CT Liver Analysis	<i>syngo</i> .CT Liver Analysis	Same
<i>syngo</i> .CT Myocardial Perfusion	<i>syngo</i> .CT Myocardial Perfusion	Same
<i>syngo</i> .CT Neuro DSA	<i>syngo</i> .CT Neuro DSA	Same
<i>syngo</i> .CT Neuro Perfusion	<i>syngo</i> .CT Neuro Perfusion	Same
<i>syngo</i> .CT Pulmo 3D	<i>syngo</i> .CT Pulmo 3D	<p style="text-align: center;">Extended</p> <p>Implementation of a software interface which provided a connection to the external medical device <i>syngo</i>.CT Lung CAD with separate clearance. Additionally, integration of the lung lobe segmentation feature which remains unchanged as compared to the reference device <i>syngo</i>.CT Extended Functionality (K203699).</p>
<i>syngo</i> .CT Skull Unfolding	<i>syngo</i> .CT Skull Unfolding	Same
<i>syngo</i> .CT Vascular Analysis	<i>syngo</i> .CT Vascular Analysis	Same

Subject Device <i>syngo</i> .CT Applications (SOMARIS/8 VB80)	Predicate Device <i>syngo</i> .CT Applications (SOMARIS/8 VB70)	Comparison Result
<i>syngo</i> .CT CaScoring	Not available in the predicate device but former separately cleared as <i>syngo</i> .CT CaScoring (K221219, clearance date 05/17/2022)	<p style="text-align: center;">Extended</p> <p>This medical device has been included to the software package <i>syngo</i>.CT Applications with no significant changes respectively changes to the clinical functionality of <i>syngo</i>.CT CaScoring. This application has been formerly cleared with K221219. Furthermore, the export function has been extended.</p>

8. 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 Applications meets the following FDA Recognized Consensus standards listed below:

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-349	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 - 3.20 2022d	12/19/2022	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1 st 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

5-129	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices 62366-1:2015+AMD1:2020	07/06/2020	AAMI, ANSI, IEC
5-134	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 Fourth edition 2021-07	12/20/2021	ISO

9. Conclusion

The fundamental scientific technology and technological characteristics are the same as the predicate device and reference device. The built-in applications in the subject device remain unchanged as the built-in ones in the predicate device except the application *syngo*.CT Pulmo 3D which includes the changes as shown in the comparison table. The additional bundling of *syngo*.CT CaScoring to the subject device and the minor improvements and enhancements do not raise questions of safety and efficacy since the changes do not introduce any new clinical algorithms/features and they do not change the performance of subject device significantly.

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 device.

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 the predicate device.