July 13, 2022

Siemens Medical Solutions USA, Inc.
% Monsuru Bello
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

Re: K221727
Trade/Device Name: syngo.CT Extended Functionality
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: June 13, 2022
Received: June 14, 2022

Dear Monsuru Bello:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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
OHT 8B: Division of Radiological Imaging Devices and Electronic Products
Office of Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221727

Device Name
syngo.CT Extended Functionality

Indications for Use *(Describe)*
syngo.CT Extended Functionality is intended to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired and reconstructed by Computed Tomography (CT) scanners, and possibly other medical imaging modalities (e.g. MR scanners).
An interface shall enable the connection between the syngo.CT Extended Functionality software package and the interconnected CT Scanner system.

Resulting images created with the syngo.CT Extended Functionality software package can be used to assist trained technicians or physicians in diagnosis.

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

I. Identification of the Submitter

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II. Device Name and Classification

Product Name:	syngo.CT Extended Functionality
Propriety Trade Name:	syngo.CT Extended Functionality
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 Devices

Predicate Device

Trade Name:	syngo.CT Extended Functionality
510(k) Number:	K214019
Clearance Date:	01/20/2022
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

syngo.CT Extended Functionality is a software bundle that offers tools to support special clinical evaluations. The "tools" are represented by the so-called Extensions. syngo.CT Extended Functionality can be used to create advanced visualizations and measurements on clinical data that was acquired and reconstructed by Computed Tomography (CT) scanners or other medical imaging modalities (e.g. MR scanners) by using the Extensions. Advanced visualizations and measurements are listed as follows. The subject device in the current software version SOMARIS/8 VB70 has been extended/modified as follows:

- Support of the extension "Average"
- Modifications to the extension "Vessel"
- Modifications to the extension "Interactive Spectral Imaging"
- Modifications to the extension "Oncology"
- "Trauma" Extension – No changes
- "Osteo" Extension – No changes
- "Neuro DSA" Extension – No changes
- "ROI HU Threshold" Extension – No changes
- "Dual Energy" Extension – No changes
- "Endoscopic Viewing" Extension – No changes
- "Pulmonary Density" Extension – No changes
- "General" (Extension Independent Features) – No changes

V. Indications for Use

syngo.CT Extended Functionality is intended to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired and reconstructed by Computed Tomography (CT) scanners, and possibly other medical imaging modalities (e.g. MR scanners).

An interface shall enable the connection between the syngo.CT Extended Functionality software package and the interconnected CT Scanner system.

Resulting images created with the syngo.CT Extended Functionality software package can be used to assist trained technicians or physicians in diagnosis.

VI. Comparison of Technological Characteristics with the Predicate Device

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

Feature	Subject Device	Predicate Device
	syngo.CT Extended Functionality *(SOMARIS/8 VB70)*	syngo.CT Extended Functionality *(SOMARIS/8 VB60)*
1. Average	The extension offers the possibility to average on a pixel-by-pixel basis of two different DICOM images. The "Average" functionality can be used on individual frames of the same series, or for frames belonging to different series. The tool saves a DICOM image as result series. This extension does not introduce any new clinical algorithms or features.	N/A
2. Vessel Extension	The user can perform a vascular evaluation supporting the following main functionalities: • Measuring vessels • Creating DICOM snapshots or result series for documenting findings • Working on images that are acquired with CT or MR scanner systems constituting one or more volumes of vascular structures **Modification**: Improved quality of the bone removal algorithm for the head & neck region. Segmentation of the bones use a deep learning algorithm instead of a traditional image processing.	The user can perform a vascular evaluation supporting the following main functionalities: • Measuring vessels • Creating DICOM snapshots or result series for documenting findings • Working on images that are acquired with CT or MR scanner systems constituting one or more volumes of vascular structures
3. Interactive Spectral Imaging	Display different representations of Dual Energy data. **Modifications:** Support of circular and elliptic ROIs. In VB70 version the measurement tool supports all others ROIs (ROI Circle (incl. elliptic) / ROI Freehand / ROI Auto Contour / ROI Polygonal).	Display different representations of Dual Energy data.
4. Oncology	The oncology extension offers tools for localization and evaluation of nodules. **Modifications:** With SOMARIS/8 VB70, the spectral information displayed for circular ROIs was extended to arbitrarily shaped ROIs.	The oncology extension offers tools for localization and evaluation of nodules.

The remaining functions in syngo.CT Extended Functionality remain unchanged compared to the predicate version.

- Trauma- displays of sorted large number of reconstruction series into body region specific layouts.
- Osteo Extension - Evaluation of Bone Mineral Density (BMD) values (mg CA-HA/ml).
- Neuro DSA Extension - Selective bone removal from a CT angiography dataset

- ROI HU Threshold Extension – Evaluation of HU Value distributions
- Dual Energy Extension – Simultaneous evaluation for low and high kV dual energy images
- Endoscopic Viewing Extension – Interactive fly through tubular structures that are filled by either low-intensity or high-intensity material
- Pulmonary Density – Segmentation of opacity regions inside the lung using an AI algorithm.

The core modification of the subject device as compared to its predicate device (syngo.CT Extended Functionality (SOMARIS/8 VB60)) are the modifications shown in the table above.

VII. Performance Data

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

Non-Clinical Testing

This submission contains performance tests (Non-clinical test reports) to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT Extended Functionality during product development. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

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 Extended Functionality will meet the following voluntary standards covering electrical and mechanical safety listed below, prior to introduction into interstate commerce:

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)/A1:2016	01/14/2019	AAMI, ANSI, IEC
5-125	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Third Edition 2019-12	12/23/2019	ISO
5-129	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2016	07/06/2020	ANSI, AAMI, IEC
5-117	General I (QS/RM)	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements 15223-1:2016	8/21/2017	ISO

VIII. Conclusion

syngo.CT Extended Functionality has the same intended use and same indications for use as the predicate device. 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 Extended Functionality, Siemens used the same testing with the same workflows as used to clear the primary predicate device. Siemens considers syngo.CT Extended Functionality to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate devices.