September 20, 2019

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

Re: K192402
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: August 29, 2019
Received: September 3, 2019

Dear Alaine Medio:

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,

Thalia T. Mills, Ph.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192402

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.

Result 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K192402

510(K) SUMMARY
FOR
SYNGO.CT EXTENDED FUNCTIONALITY

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: September 18, 2019

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. Submitter

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Siemens Medical Solutions USA, Inc.
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2240869

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Tabitha Estes

II. Device Name and Classification

Product 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 Device

Primary Predicate Device:

Trade Name:	syngo.CT Clinical Extensions
510(k) Number:	K173625
Clearance Date:	03/08/2018
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	There are currently no recalls for this device

Secondary Predicate Device:

Trade Name:	syngo.CT Dual Energy
510(k) Number:	K150757
Clearance Date:	08/11/2015
Classification Name:	System, Image Processing, Radiological
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	There are currently no recalls for this device

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. In addition, the table below shows which extensions has been changed in the current software version SOMARIS/8 VB40.

No	Extension	No	Extension
1	Interactive Spectral Imaging (new)	5	Neuro DSA (unmodified)
2	Vascular/Vessel Extension (modified)	6	ROI HU Threshold (unmodified)
3	Oncology Extension (modified)	7	Dual Energy (unmodified)
4	Osteo (unmodified)	8	Endoscopic View (unmodified)

syngo.CT Extended Functionality is an extension of the previously cleared primary predicate device post-processing application software syngo.CT Clinical Extensions (K173625) and includes the following modifications in comparison to the primary predicate device:

a. Support of Interactive Spectral Imaging
b. Vascular Extension modification:
    i. 2D Filter Type Support
    ii. Multiphase Support in Vessel Layout
c. Oncology Extension modification:
    i. Support of MR Data
d. General: Multiphase support for merged 4D series

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.

Result 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 indications for use for the syngo.CT Extended Functionality are identical to the predicate device Indications for Use (see Table 2). The only difference is the renaming of the feature from syngo.CT Clinical Extensions to syngo.CT Extended Functionality. The intended use of this product is identical to the predicates.

Table 2: Indications for Use / Intended Use Comparison

Subject Device **syngo.CT Extended Functionality**	**Predicate Device (K173625)** **syngo.CT Clinical Extensions**	**Comparison Result**
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. Result images created with the syngo.CT Extended Functionality software package can be used to assist trained technicians or physicians in diagnosis.	syngo.CT Clinical Extensions 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 Clinical Extensions software package and the interconnected CT Scanner system. Result images created with the syngo.CT. Clinical Extensions software package can be used to assist trained technicians or physicians in diagnosis.	Identical with the exception of the name of the product.

As with the primary predicate device, the subject device is a bundle software package consisting of previously cleared software applications (unmodified and modified) that provide advanced visualization and measurement tools.

Software version SOMARIS/8 VB40 supports additional post-processing application features for MR datasets, dual energy images, and endoscopic visualization tools. At a high-level, the subject and predicate devices are based on the following same or similar technological characteristics as listed in **Table 3** below:

Table 3: Technological Characteristic Comparison

Feature	Subject Device syngo.CT Extended Functionality	Predicate Device and Supported Functionality	Comparison Result
Software Version	SOMARIS/8 VB40	**Primary Predicate Device:** K173625, clearance date 03/08/2018 SOMARIS/8 VB30	Modified to support additional functionality
1. Interactive Spectral Imaging			
Interactive Spectral Imaging	The Interactive Spectral Imaging functionality allows the user to display different representations of Dual Energy data with an interactive image text.	**Secondary Predicate Device** K150757, clearance date 08/11/2015 The user can change the visualization of Dual Energy data generated from Low and High data to different Dual Energy types.	This feature is new in the subject device, but the fundamental technology has been cleared with the secondary predicate device.
2. Vascular/Vessel Extension			
Vascular/ Vessel Extension	The Vascular Tool provides tools and layouts for vascular assessment. Additionally, the subject device Vascular Tool provides a *2D Filter Type Support* and *Multiphase Support in Vessel Layout.*	**Primary Predicate Device:** K173625, clearance date 03/08/2018 The Vascular Tool provides tools and layouts for vascular assessment and CT data.	This modification is a usability improvement.
3. Oncology Extension			
Oncology Extension	The oncology Tool offers tools for localization and evaluation of nodules. Additionally, the subject device now provides *MR Support for Diameter WHO.*	**Primary Predicate Device:** K173625, clearance date 03/08/2018 The oncology extension offers tools for localization and evaluation of nodules.	Modified to support MR data for Diameter WHO.
4. Osteo Extension			
Osteo Extension	The Osteo extension is used for the evaluation of Bone Mineral Density (BMD) values (mg CA-HA/ml) of the lumbar spine based on Osteo CT scans.	**Primary Predicate Device:** K173625, clearance date 03/08/2018 The Osteo extension is used for the evaluation of Bone Mineral Density (BMD) values (mg CA-HA/ml) of the lumbar spine based on Osteo CT scans.	Same – There are no modifications.
5. Neuro DSA Extension			
Neuro DSA Extension	Bone removal tool from a CT angiography dataset.	**Primary Predicate Device:** K173625, clearance date 03/08/2018 Bone removal tool from a CT angiography dataset.	Same – There are no modifications.
6. Dual Energy ROI			
Dual Energy ROI	Evaluation of low/high kV images from dual energy data.	**Primary Predicate Device:** K173625, clearance date 03/08/2018 Evaluation of low/high kV images from dual energy data.	Same – There are no modifications.
7. Endoscopic View			
Endoscopic View Tool	Fly through tubular structures which are either filled by low-intensity (e.g. air-filled) or high-intensity (e.g. blood-filled) material.	**Primary Predicate Device:** K173625, clearance date 03/08/2018 Fly through tubular structures which are either filled by low-intensity (e.g. air-filled) or high-intensity (e.g. blood-filled) material.	Same – There are no modifications.

Feature	Subject Device syngo.CT Extended Functionality	Predicate Device and Supported Functionality	Comparison Result
8. ROI HU Threshold			
ROI HU Threshold	Evaluation of HU value distributions within a user defined region of interest.	**Primary Predicate Device:** K173625, clearance date 03/08/2018 Evaluation of HU value distributions within a user defined region of interest	Same – There are no modifications.
General, Extension-independent Functionality			
Pre-generated results	Support of pre-generated results and the ability to edit pre-generated results	**Primary Predicate Device:** K173625, clearance date 03/08/2018 Support of pre-generated results and the ability to edit pre-generated results	Same – There are no modifications.
Multiphase support for merged 4D series	Grouping of multiphase series generated by respiratory gated, perfusion and cardiac datasets.	**Primary Predicate Device:** K173625, clearance date 03/08/2018 Grouping of multiphase series generated by respiratory gated and perfusion datasets.	Usability improvement: The grouping logic has been extended to include cardiac gated datasets.

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation is completed. Test results show that the subject device, syngo.CT Extended Functionality are comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

VII. Performance Data

Software Verification and Validation Testing
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 included as part of this submission.

Non-Clinical / Clinical Testing Summary
syngo.CT Dual Energy is designed to fulfill the requirements of the following safety and performance standards:

Recognition Number	Product Area	Title of Standard	Publication Date	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-32	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)	08/20/2012	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	08/20/2012	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	IEC

Performance tests were conducted to test the Interactive Spectral Imaging (ISI) functionality of the syngo.CT Extended Functionality post-processing application. A phantom-based validation *"Detailed Description and Bench*

Tests for the Plugin "Interactive Spectral Imaging"" has been conducted to show that the feature ISI operates as intended.

Non-clinical tests and a phantom-based bench test have been conducted to establish the proficiency of the 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.

General Safety and Effectiveness Concerns
The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing.

VIII. Conclusions

syngo.CT Extended Functionality has the same intended use and same indication for use as the primary predicate device. The technological characteristics such as image visualization, operating platform, and image measurement are the same as the predicate devices. 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.