DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Blvd., Mail Code 65-1A
MALVERN PA 19355

Re: K163341
Trade/Device Name: syngo.CT Extended Functionality
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 17, 2016
Received: November 29, 2016

Dear Ms. Mangum:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163341

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.

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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SIEMENS

510(K) SUMMARY
FOR
SYNGO.CT EXTENDED FUNCTIONALITY

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

Date Prepared: January 24, 2017

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

Establishment Registration Number
2240869

Manufacturing Site
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II. Device Name and Classification

510(k) Number:	K163341
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:	90JAK

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III. Predicate Device

Predicate Device:

Trade Name:	syngo.CT Vascular Analysis
510(k) Number:	K112020
Clearance Date:	08/18/2011
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	JAK

Predicate Device:

Trade Name:	syngo.CT Lung CAD
510(k) Number:	K143196
Clearance Date:	05/12/2015
Classification Name:	Lung Computed Tomography System, Computer-Aided Detection
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.2050
Device Class:	Class II
Product Code:	OEB

Predicate Device:

Trade Name:	Osteo CT Option for SOMATOM CT Systems
510(k) Number:	K971054
Clearance Date:	06/13/1997
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	JAK
Subsequent Product Code:	KGI

Predicate Device:

Trade Name:	syngo Neuro DSA CT
510(k) Number:	K053024
Clearance Date:	11/04/2005
Classification Name:	System, X-Ray, Tomography, Computed
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 consisting of previously cleared unmodified and modified post-processing applications that offer tools to support special clinical evaluations. 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.

Depending on the clinical question, the user can select functionality which supports the explicit clinical fields as listed below. The syngo.CT Extended Functionality software

package is designed to operate on the most recent version syngo-compatible post-processing platform, which currently supports the following four tools:

1. Preparation of Vascular Case for Reading Physician
2. Preparation of Oncology Case for Reading Physician
3. Preparation of Osteo Case for Reading Physician
4. Preparation of Neuro DSA Bone Subtraction for Reading Physician

The supported functionality can be used on any CT data if basic requirements are met (e.g. spiral or sequence scan, reconstruction kernel). The supported functionality will check to ensure the basic requirements are met and will not allow its execution or will provide a warning or info message to the user if appropriate. This check also allows combination of functionality of different clinical fields, (e.g. a vascular case can be prepared also on Neuro DSA bone subtracted data or on the same case as Lung CAD computation, etc.). Afterwards, any tool can be accessed as long as the data and viewing type allows it. For example, an evaluation of a ROI defined by a contour and two HU thresholds can be used to measure a certain area. No specific sequential workflow is required.

The original clinical data that was acquired and reconstructed by Computed Tomography (CT) scanners will not be modified in any form. The results of the syngo.CT Extended Functionality can be stored as additional DICOM images if needed as key images or range or images. The subject device syngo.CT Extended Functionality is designed to operate on a syngo compatible host system (e. g. syngo.via VB20 software platform or higher).

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.

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

This subject device is a bundle software package consisting of previously cleared unmodified and modified software applications that provide advanced visualization and measurement tools. At a high-level, the subject and predicate device are based on the following same/similar technological characteristics:

Subject Supported Functionality	Predicate Device and Supported Functionality	Comparison Results
Tools and layouts for vascular assessment	**predicate device:** K112020 - syngo.CT Vascular Analysis Tools and layouts for vascular assessment	Supports the same unmodified functionality from the predicate device.
Display of the findings of the Lung CAD algorithm	**predicate device:** K143416 – syngo.CT Lung CAD	Supports the same unmodified functionality

Subject Supported Functionality	Predicate Device and Supported Functionality	Comparison Results
	Display of the findings of the Lung CAD algorithm	from the predicate device.
Provides a set of routine tools for the assessment of bone mineral content	**predicate device:** K971054 - Osteo CT Option for SOMATOM CT Systems Provides a set of routine tools for the assessment of bone mineral content	Modified to evaluate images from volume scans and semi-automatically calculate the position and orientation of mid-vertebral slices (MVS).
Provides a set of tools for assessment of the cerebral vasculature by removing interfering bone structures	**predicate device:** K971054 Provides a set of tools for assessment of the cerebral vasculature by removing interfering bone structures	Supports the same unmodified functionality from the predicate device.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination. This submission contains performance data 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. The modifications described in this Premarket Notification were supported with verification/validation testing. Verification and Validation testing for the Osteo feature was conducted to demonstrate successful software integration and performance in accordance to Siemens internal procedure which includes risk identification and mitigation in accordance with ISO 14971. All verification and validation testing has been completed and meets Siemens acceptance criteria. Additionally, all risks for the complete subject device have been identified and mitigated in accordingly.

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.

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.

Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of the syngo.CT Extended Functionality. 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.

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.

syngo.CT Extended Functionality 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
5-95	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	06/27/2016	IEC
19-4	General II (ES/EMC)	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod)	07/09/2014	AAMI, ANSI

VIII. Conclusions

This subject device combines four advanced visualization and measurement tools into one software bundle package. The fundamental software technology which is provided within the scope of the advanced tools is already cleared and remains unchanged in comparison to the predicate devices. The Indications for Use for the subject device has been adapted to provide a more specific description of the syngo.CT Extended Functionality realized as software package including a software bundle that consists of previously cleared post-processing software applications. The conducted modifications described in this Premarket Notification were supported with verification and validation testing. The Risk analysis was completed and risk control implemented to mitigate identified hazards.

The predicate devices were cleared based on non-clinical supportive information. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The comparison of technological characteristics, non-clinical performance data, 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 Extended Functionality, Siemens used the same testing with the same workflows as used to clear the predicate device. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.CT Extended Functionality testing supports a finding of substantial equivalence.