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

March 8, 2018

Re: K173625
Trade/Device Name: syngo.CT Clinical Extensions
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 30, 2018
Received: February 1, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173625

Device Name

syngo.CT Clinical Extensions

Indications for Use *(Describe)*

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.

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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510(K) SUMMARY
FOR
SYNGO.CT CLINICAL EXTENSIONS

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: March 6, 2018

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
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Establishment Registration Number
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II. Device Name and Classification

Product Name:	syngo.CT Clinical Extensions
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

III. Predicate Device
Primary Predicate Device:

Trade Name:	syngo.CT Extended Functionality
510(k) Number:	K163341
Clearance Date:	02/09/2017
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:	This predicate has not been subject to a design-related recall

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Secondary Predicate Device:

Trade Name:	syngo.CT Single Source Dual Energy
510(k) Number:	K150745
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:	This predicate has not been subject to a design-related recall

Secondary Predicate Device:

Trade Name:	syngo Fly Through
510(k) Number:	K971717
Clearance Date:	09/03/1997
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:	This predicate has not been subject to a design-related recall

Secondary Predicate Device:

Trade Name:	syngo.MR Vascular Analysis
510(k) Number:	K130749
Clearance Date:	08/20/2013
Classification Name:	System, Image Processing, Radiological
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.2050
Device Class:	Class II
Product Code:	LLZ
Subsequent Product Code	LNH
Recall Information:	This predicate has not been subject to a design-related recall

Reference Device:

Trade Name:	syngo.PET&CT Oncology
510(k) Number:	K093621
Clearance Date:	02/23/2010
Classification Name:	System, Image Processing, Radiological
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.2050
Device Class:	Class II
Product Code:	LLZ
Recall Information:	This reference device has not been subject to a design-related recall

Reference Device:

Trade Name:	syngo.CT Coronary Analysis
510(k) Number:	K100637
Clearance Date:	05/26/2010
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:	This reference device has not been subject to a design-related recall

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IV. Device Description

syngo.CT Clinical Extensions is a software bundle that offers tools to support special clinical evaluations. syngo.CT Clinical Extensions 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). syngo.CT Clinical Extensions is an extension of the previously cleared primary predicate device post-processing application software syngo.CT Extended Functionality and includes the following modifications in comparison to the primary predicate device:

1. New Marketing Name: syngo.CT Clinical Extensions
2. Modified Indications for Use Statement
3. Support of software version SOMARIS/8 VB30 which supports the following functionality:
    a. Vascular Tool modification:
        i. Modified Coronary Vessel Tracing Support
        ii. Heart and Coronary Tree Isolation Tools
        iii. Support of MR data
        iv. Support of additional workflow improvement visualization tools
    b. Oncology Tool modification:
        i. Support of Mean Diameter Value
        ii. Support of Lung Lesion Segmentation Tool
    c. Support of Dual Energy Tool
    d. Support of Endoscopic View Tool
    e. Editing of Pre-generated Results

Depending on the clinical question, the user can select functionality which supports the explicit clinical fields as listed below. The syngo.CT Clinical Extensions software package is designed to operate on syngo-compatible post-processing platforms, software version SOMARIS/8 VB30 or later. **Table 1** below provides a listing of all tools as well as the modification status in comparison to the predicate devices for this software version:

Table 1: syngo.CT Clinical Extensions Tool Packages

Tool	Description	Modification Status
Vascular Tool	Provides tools and layouts for vascular assessment. This feature has been modified from the predicate primary device to support the following: • Semi-automatic vessel tracing tool that allows tracing with less user-interaction • Heart and Coronary Tree isolation tools that allow removal and isolation of myocardial structures • Support of MR Angiography data • Workflow improvement tools that allow management and documentation of measurements	Modified from the primary predicate device
Oncology Tool	Provides tools for localization and evaluation of nodules. This feature has been modified from the predicate primary device to support the following: • Mean Diameter Value Tool that allows display of the mean diameter of a lesion • Lung Lesion Segmentation Tool that allows semi-automatic segmentation of solid and sub-solid nodules. The unmodified Lung Lesion Segmentation Tool was cleared in a reference device under K093621.	Modified from the primary predicate device
Osteo Tool	Provides a set of routine tools for the assessment of bone mineral content.	Unmodified from the primary predicate device

Tool	Description	Modification Status
Neuro DSA Tool	Provides a set of tools for assessment of the cerebral vasculature by removing interfering bone structures.	Unmodified from the primary predicate device
Dual Energy Tool	Provided tools for the Evaluation of low/high kV images from dual energy data.	Newly supported but unmodified from the secondary predicate device
Endoscopic View Tool	Provides the possibility to interactively fly through tubular structures which are either filled by low-intensity (e. g. air-filled) or high-intensity (blood filled) material.	Newly supported but unmodified from the secondary predicate device
ROI HU Threshold Tool	Supports the user in the evaluation of HU value distributions within a user defined region of interest.	Unmodified from the primary predicate device

V. Indications for Use

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.

VI. Comparison of Technological Characteristics with the Predicate Device

As with the primary predicate device, the subject device is a bundle software package consisting of previously cleared unmodified and modified software applications that provide advanced visualization and measurement tools. Software version SOMARIS/8 VB30 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 2** below:

Table 2: Technological Characteristic Comparison

Feature	Subject Device syngo.CT Clinical Extensions	Predicate Device and Supported Functionality	Comparison Result
Software Version	SOMARIS/8 VB30	**Primary Predicate Device:** K163341, clearance date 2/9/2017 SOMARIS/8 VB20	Modified to support additional functionality
Vascular Tool	The Vascular Tool provides tools and layouts for vascular assessment. Additionally, the subject device Vascular Tool supports additional tools for vascular assessment and support of MR data.	**Primary Predicate Device:** K163341, clearance date 2/9/2017	Modified to support additional assessment tools and MR data

		The Vascular Tool provides tools and layouts for vascular assessment and CT data.	
Oncology Tool	The oncology Tool offers tools for localization and evaluation of nodules. Additionally, the subject device provides the possibility to calculate the mean diameter value and supports lung lesion segmentation tools.	**Primary Predicate Device:** K163341, clearance date 2/9/2017 The oncology extension offers tools for localization and evaluation of nodules.	Modified to support mean value calculation and lung lesion segmentation tools
Osteo Tool	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:** K163341, clearance date 2/9/2017. 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.	Unmodified from the primary predicate device
Neuro DSA Tool	Bone removal tool from a CT angiography dataset.	**Primary Predicate Device:** K163341, clearance date 2/9/2017. Bone removal tool from a CT angiography dataset.	Unmodified from the primary predicate device
Dual Energy Tool	Evaluation of low/high kV images from dual energy data.	**Secondary Predicate Device:** K150745, clearance date 8/11/2015 Evaluation of low/high kV images from dual energy data.	Unmodified from the secondary predicate device K150745
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.	**Secondary Predicate Device:** K971717, clearance date 9/3/1997 Fly through tubular structures which are either filled by low-intensity (e.g. air-filled) or high-intensity (e.g. blood-filled) material.	Unmodified from the secondary predicate device K971717
ROI HU Threshold Tool	Evaluation of HU value distributions within a user defined region of interest.	**Primary Predicate Device:** K163341, clearance date 2/9/2017.	Unmodified from the primary predicate device

		Evaluation of HU value distributions within a user defined region of interest	
Pre-generated results	Support of pre-generated results and the ability to edit pre-generated results	**Primary Predicate Device:** K163341, clearance date 2/9/2017. Support of pre-generated results	Modified from the primary predicate device to support editing of pre-generated results

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Siemens believes that the subject device is substantially equivalent to the predicate devices. Testing and validation is completed. Test results show that the subject device, syngo.CT Clinical Extensions 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

Non-Clinical Testing Summary

Non-clinical tests (integration and functional) were conducted for syngo.CT Clinical Extensions during product development. Performance tests were conducted to test the functionality of the syngo.CT Clinical Extensions. The modifications described in this Premarket Notification were supported with verification/validation testing. 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. Siemens claims conformance to the following performance standards listed in **Table 3**:

Table 3: Conformance 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

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 supports the claim of substantial equivalence.

Siemens Healthcare conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014" is included within this submission.

Summary
This subject device combines seven 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 subject device syngo.CT Clinical Extensions functionality, but does not represent a new intended use in comparison to the predicate devices. The 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.

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 Clinical Extensions is designed to fulfill the requirements of the applicable safety and performance standards as listed above.

VIII. Conclusions
The predicate devices were cleared based on non-clinical testing including verification and validation, and supportive literature. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The subject device is also tested using the same methods as used for the predicate devices. The comparison of technological characteristics, non-clinical performance data, and software validation included in this submission demonstrates that the subject device is as safe and effective when compared to the predicate devices that are currently marketed for the same intended use. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.CT Clinical Extensions testing supports a finding of substantial equivalence.