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

November 6, 2019

Re: K191891
Trade/Device Name: SOMATOM X.cite
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: October 3, 2019
Received: October 4, 2019

Dear Ms. Estes:

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,

For

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)*

K191891

Device Name
SOMATOM X.cite

Indications for Use *(Describe)*

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

The images delivered by the system can be used by a trained physician as an aid in diagnosis.
The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K191891

Device Name
Scan & Go

Indications for Use *(Describe)*

This in-room scan application is a planning and information system designed to perform the necessary functions required for planning and controlling scans of supported SIEMENS CT scanners. It allows users to work in close proximity to the scanner.

The in-room scan application runs on standard information technology hardware and software, utilizing the standard information technology operating systems and user interface. Communication and data exchange are done using special protocols.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
FOR
SOMATOM X.CITE
– SOFTWARE VERSION SOMARIS/10 syngo CT VA30

Submitted by:
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932
Date Prepared: July 12, 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

Siemens Medical Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932
Establishment Registration Number
1034973

Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number
2240869

Location of Manufacturing Site (1)
Siemens Healthcare GmbH
Siemensstr. 1
D-91301 Forchheim, Germany
Establishment Registration Number
3004977335

Location of Manufacturing Site (2)
SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD
278 Zhou Zhu Rd
Shanghai, CHINA, 201318
Establishment Registration Number:
3003202425

Contact Person:
Tabitha Estes
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932
Phone: (865) 804-4553
Fax: (865) 218-3019
Email: tabitha.estes@siemens-healthineers.com

II. Device Name and Classification

Product Name:	SOMATOM X.cite
Trade Name:	SOMATOM X.cite
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Product Name:	Scan&GO
Propriety Trade Name:	Scan&GO
Classification Name:	Computed Tomography X-ray System
Secondary Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Secondary CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	JAK
Secondary Product Code:	LLZ

III. Predicate Device

Primary Predicate Device:

Trade Name:	SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.Top, SOMATOM go.All, Scan&GO
510(k) Number:	K173632
Clearance Date:	April 13, 2018
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All predicate device recalls have been considered in the subject device design.

Note: K173632 was a bundle submission with various Siemens CT Scanner Systems. In this submission the predicate devices SOMATOM go.Now, SOMATOM go.Top and Scan&GO are applicable, to demonstrate substantial equivalence of technological characteristics.

Predicate Device:

Trade Name:	SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS Open, SOMATOM Edge Plus, SOMATOM Definition AS/AS+, SOMATOM Confidence
510(k) Number:	K190578
Clearance Date:	June 27, 2019
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	There are currently no recalls for this device

Note: K190578 was a bundle submission with various Siemens SOMATOM CT Scanner Systems. In this Submission the predicate devices SOMATOM Force and SOMATOM Edge Plus are applicable, to demonstrate substantial equivalence of technological characteristics.

IV. Device Description

Siemens intends to market a new software version, SOMARIS/10 syngo CT VA30 for Siemens SOMATOM X.cite (CT) Scanner System with mobile workflow options.

Single Source CT Sacnner System:

- SOMATOM X.cite
- Scan&GO Mobile Medical Application (optional mobile workflow component)

The subject device SOMATOM X.cite with SOMARIS/10 syngo CT VA30 is a Computed Tomography X-ray System which feature one (single source) continuously rotating tube-detector system and function according to the fan beam principle. The SOMATOM X.cite with Software SOMARIS/10 syngo CT VA30 produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens Healthcare and other vendors as an aid in diagnosis, treatment preparation and therapy planning support (including, but not limited to, Brachytherapy, Particle including Proton Therapy, External Beam Radiation Therapy, Surgery). The computer system delivered with the CT scanner is able to run optional post processing applications.

The Scan&GO mobile workflow is an optional planning and information software designed to perform the necessary functions required for planning and controlling of the workflow of the SOMATOM X.cite CT scanner. Scan&GO can be operated on a Siemens provided tablet or a commercially available tablet that meets certain minimum technical requirements. It allows users to work in close proximity to the scanner and the patient. Specifically Scan&GO allows control/display of the following software interactions via a wireless tablet that meets certain minimum requirements:

- Selection of patients
- Selection of pre-defined protocols
- Scan parameter display
- Patient table position display and gantry tilt parameter display
- Tools and instruction message area,
- Patient table position planning area
- Physiological data display
- Patient data display (e.g. date of birth, name)
- Display of acquired topogram and tomogram images
- Finalization of exam (close patient)
- Mobile Organizer,
- Patient Instruction Language (“API languages”)
- Interface to support control function for RTP Laser (e.g. LAP Laser)
- Control of moodlight functions
- predefined workflow associated question/answer dialog

NOTE: Scan&GO does not support storage of images. Additionally, Scan&GO cannot trigger a scan or radiation release.

The software version for the SOMATOM X.cite, syngo CT VA30 (SOMARIS/10 syngo CT VA30), is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The software platform SOMARIS/10 syngo CT VA30 is designed to provide a plugin interface to support the optional Scan&GO mobile workflow as well as integrate potential advanced post processing tasks, tools, or extendable functionalities. Software version syngo CT VA30 (SOMARIS/10 syngo CT VA30) is a new software version based on syngo CT VA20A (SOMARIS/10 syngo CT VA20) which was cleared for the primary predicate devices in K173632), and supports the same plugin interfaces for the optional Scan&GO mobile workflow and integration of post-processing tasks as the predicate devices.

The SOMATOM X.cite will support the following modifications/further developments in comparison to the predicate devices:

1) New/Modified Hardware

- Table S01: Overview of Hardware modifications supported by software SOMARIS/10 syngo CT VA30

2) Software version SOMARIS/10 syngo CT VA30

- Table S02: Overview Software modifications of SOMATOM X.cite with syngo CT VA30

The submission show configuration table and comparison table and use the following Terms to describe various technological characteristics in comparison to the predicate device information:

Term	Definition
N/A	The feature is not supported for the subject device
New	The feature is newly supported for Siemens CT Scanners and the subject device
Modified	This feature is modified from the previously cleared version
Unmodified	This feature remains unchanged from the predicate device
Enabled	This feature is currently supported by other cleared Siemens CT systems. This feature will be supported for the subject device with software version SOMARIS/10 syngo CT VA30 and is unmodified from cleared version.

Table S01: Overview of ***Hardware Modifications*** *supported by software SOMARIS/10 syngo CT VA30*

	SOMATOM X.cite with SOMARIS/10 syngo CT VA30	**Subject Device**	**Subject Device**
#	**hardware properties**	**SOMATOM X.cite**	**Scan&GO**
1	Patient Observation Camera	Modified	N/A
2	Moodlight	Modified	N/A
3	Various Tablet Configuration	Modified	Modified
4	High Power 70 / High Power 80	Enabled	N/A
5	Adaptive Dose Shield	Enabled	N/A
6	Tin Filter	Enabled	N/A
7	Split Filter	Modified	N/A
8	3D Camera	Enabled	N/A
9	Other hardware modifications (e.g. new bore size, enabled Vectron™ Tube)	Modified	N/A

Table S02: *Overview* ***Software modifications*** *of SOMATOM X.cite with syngo CT VA30*

	SOMATOM CT System Scanner with SOMARIS/10 syngo CT VA30	**Subject Devices**	**Subject Device**
#	**Software properties**	**SOMATOM X.cite**	**Scan&GO**
1	MPPS	Enabled	N/A
2	Flex Dose Profile	Modified	N/A
3	Flex 4D Spiral	Modified	N/A
4	DirectDensity™	Enabled	N/A
5	Scan&GO – Mobile Workflow	Modifed	Modified
6	CT View&GO – Advanced tools	Modified	N/A
7	Check&GO – Metal Detection	New	New
8	CARE Contrast III and Contrast media protocol	Modified	N/A
9	CARE kV	Modified	N/A
10	kV and Filter independent CaScore (Artificial120)	Enabled	N/A
11	Recon&GO – Advanced Reconstruction	Modified	N/A
12	Recon&GO – Post-Processing plug in functions	Modified	N/A
13	TwinBeam Dual Energy	Modified	N/A
14	TwinSpiral Dual Energy	Modified	N/A
15	FAST Planning, FAST Window	Modified	N/A
16	HD FoV 4.0	Enabled	N/A
17	Imaging – workflow decision tree	New	New
18	Imaging - Cardio BestPhase	Enabled	N/A
19	Multistudy	Modified	N/A
20	Multiphase	Modified	N/A
21	Respiratory Motion Management	Enabled	N/A
22	Patient Marking - Direct Laser Steering	New	New
23	Automatic Patient Instruction	Modified	N/A
24	FAST Integrated Workflow (including FAST 3D Camera)	Modified	N/A
25	ADMIRE	Enabled	N/A

A comparison of these modifications with respect to the predicate devices is provided in the "**Comparison of Technological Characteristics with the Predicate Device**" section below.

V. Indications for Use

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

The images delivered by the system can be used by a trained physician as an aid in diagnosis.
The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Scan&GO:
This in-room scan application is a planning and information system designed to perform the necessary functions required for planning and controlling scans of supported SIEMENS CT scanners. It allows users to work in close proximity to the scanner.
The in-room scan application runs on standard information technology hardware and software, utilizing the standard information technology operating systems and user interface. Communication and data exchange are done using special protocols

VI. Comparison of Technological Characteristics with the Predicate Device

The SOMATOM X.cite scanner provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software and hardware components of these scanners have been modified or improved in comparison to the predicate devices to support enhanced device functionality.
The hardware components of the subject devices have been modified to support mobile workflow with multiple tablet configuration, a 3D Camera workflow for patient positioning, a larger bore size, modified gantry mechanics, tube and patient tables and Vectron x-ray tube.

Software version SOMARIS/10 syngo CT VA30 supports software features that are designed as Software Platform update including extended functionalities and GO technologies which provide interfaces to directly access optional post processing applications and are designed to enhance the user workflow.

The intended use and fundamental scientific technology for the SOMATOM X.cite remains unchanged from the predicate devices.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Scanner Principle- Whole body X-Ray Computed Tomography Scanner
- System Acquisition – Continuously rotating tube detector system
- Iterative Reconstruction – Support of various iterative reconstruction methods
- Workplaces – Support of workplaces that include reconstruction and image evaluation software
- Patient table
- Patient table foot switch for movement
- Tin filtration technology
- Athlon or Vectron X-ray Tube
- Stellar detector technology
- Maximum power Generator
- High Power 70, High Power 80 (High mA@low kV)
- Iterative Reconstruction Methods
- Mobile Medical application Software functionality (Scan&GO)
- Mobile workflow (Tablet)
- Support of interfaces to access 3D Camera operation for fast patient positioning workflow
- Scanner display and control functionality
- Remote Scan Control
- Support of Intervention Workflow - Guide&GO
- Optional Injector Arm

- Long scan range
- DirectDensity™ Reconstruction, which provides CT images with an HU-like scaling that is nearly proportional to relative electron density or relative mass density
- Respiratory Scan – Functions

The following technological differences exist between the subject device SOMATOM X.cite and the primary predicate device SOMATOM go.Top (K173632) and the predicate device SOMATOM Force (K190578):

- Software version SOMARIS/10 syngo CT VA30
- Support of additional cybersecurity features
- Multiple tablet configuration for enhanced mobile workflow and control functionality
- Additional options for Inline and GO technologies
- CT protocol workflow enhanced functionality for advanced examination including parameter for scan protocol and contrast media.
- Interface to RTP Lasers for direct laser steering (e.g. in combination with 3rd party LAP laser system)
- CT gantry hardware supporting large bore size and 50 cm scan field-of-view

The following technological differences exist between the subject device Scan&GO and the primary predicate device Scan&GO (K173632):

- Software version SOMARIS/10 syngo CT VA30
- Advanced workflow (including option for Direct Laser Steering e.g. for LAP or Siemens Direct Laser)
- Optional hardware support for multiple tablet configuration

A summary of the differences between the subject device CT scanner configurations is provided as **Table S03 and Table S04** below.

The tabular summary of the comparable **hardware properties** between the subject devices with software version SOMARIS/10 syngo CT VA30 and the predicate devices are listed in **Table S03** below (modifications are in gray shaded sections).

Table S03: *SOMATOM X.cite comparable hardware properties*

Hardware Property	**Device Comparison**		
	Subject Device	**Primary Predicate Devices**	**Predicate Device**
	SOMATOM X.cite	**SOMATOM go.Top (K173632)**	**SOMATOM Force (K190578)**
Scanner	whole body X-ray computed tomography scanner		
Generator max. power	105 kW	75 kW	2x 120 kW
Detector technologie	Stellar	Stellar	Stellar
Detector volumen coverage	38.4 mm	38.4 mm	2 x 57,6 mm
Detector physical rows	64	64	2 x 96
Detector slice width	0.6 mm	0.6 mm	0.6 mm
Detector DAS channel No.	840	840	736 920
Detector image slices	128	128	2 x 192
Tube Technologie	Vectron	Athlon	Vectron
Tube kV steps	(in 10kV steps) 70 kV to 150kV	(in 10kV steps) 70 kV to 140kV	(in 10kV steps) 70 kV to 150kV
Tube max. current	1200 mA	825 mA	2 x 1300 mA
Tube tube focus	0.6 x 0.7 0.8 x 1.1	1.0 x 1.2 0.8 x 0.8	0.4 × 0.5/0.6 × 0.7/0.8 × 1.1 (for both tubes)
Tube heat capacity	higher than 30 MHU	6 MHU	higher than 30 MHU
Gantry bore size	82 cm	70 cm	78 cm
Gantry FoV	50 cm	50 cm	50 cm
Gantry rotation time (sec)	0.3, 0.5, 1.0	0.33, 0.5, 1.0	0.25, 0.285, 0.33, 0.5, 1.0
Gantry Tilt [degree]	+/- 25	+/-30	N/A
Patient Table type	Vario RT: 1.600 m, Vario 2: 2.000 m	Vario 1 and Vario RT: 1.600 mm, Vario 2: 2.000 mm	PHS5, MPT4: 1.600 m or 2.000 m
Max. Scan length Topogram	1680 mm 2080 mm	1600 mm, 2000 mm	1600 mm, 2000 mm
Max. Scan length Image acquisition	1600 mm, 2000 mm	1600 mm, 2000 mm	1600 mm, 2000 mm
Spectral filtration Option*	Combined Split Filter / Tin Filter supported, plus extra Tin Filter	Combined Split Filter / Tin Filter supported	Tin Filter for both tubes
3D Camera for patient positioning	option for patient positioning with 3D Camera	N/A	option for patient positioning with 3D Camera
High Power 70	1200 mA (@ 70 kV)	825 mA (@ 70 kV)	1300 mA (@ 70 kV)
High Power 80	1200 mA (@ 80 kV)	825 mA (@ 80 kV)	1300 mA (@ 80 kV)

The tabular summary of the comparable **software properties** between the subject devices with software version SOMARIS/10 syngo CT VA30 and the predicate devices are listed in **Table S04** below (modifications are in gray shaded sections).

Table S04: *SOMATOM X.cite comparable software properties*

Properties software	*Subject Device*	*Primary Predicate Device*	*Predicate Device*
	SOMATOM X.cite	**SOMATOM go.Top**	**SOMATOM Force**
	(syngo CT VA30)	**(K173632)**	**(K190578)**
Operating System	Windows based SOMARIS/10 syngo CT VA30	Windows based SOMARIS/10 syngo CT VA20A	Windows based SOMARIS/7 syngo CT VB20
Acquisition Workplace	syngo Acquisition Workplace (AWP)	syngo Acquisition Workplace (AWP)	syngo Acquisition Workplace (AWP)
	syngo Viewing, syngo Filming and syngo Archiving & Networking	syngo Viewing, syngo Filming and syngo Archiving & Networking	syngo Viewing, syngo Filming and syngo Archiving & Networking
	Image Reconstruction	Image Reconstruction	Image Reconstruction
Stellar Detector	Stellar detector firmware supported	Stellar detector firmware supported	Stellar detector firmware supported
Teamplay	Support teamplay Protocols	Support teamplay Protocols	Support teamplay Protocols
Protocols (Single Source CT Scanner System)	Support of : • Protocols for Radiation Therapy Planning support patient marking • Protocols that allow scanning with support of an external respiratory gating system (ANZAI, Varian RGSC) • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols • Pediatric Protocols • Flex Dose Profile • TwinBeam DE • TwinSpiral DE • Flex 4D Spiral	Support of : • Protocols for Radiation Therapy Planning • Protocol supporting contrast bolus-triggered data acquisition • Pediatric Protocols	Support of : • Protocols for Radiation Therapy Planning • Protocols for Radiation Therapy Planning • Protocols that allow triggering of breath hold scanning from external device. • Protocol supporting contrast bolus-triggered data acquisition • Pediatric Protocols • Adaptive Dose Area • DualSource DE • Adaptive 4D Spiral
post-processing methods (syngo CT VA30 enable a subset of methods on the scanner software installation – only applicable for previously cleared syngo applications)	enabled via software interface Recon&GO - Inline Results **varies methods contained in the available applications** syngo.CT Coronary Analysis syngo.CT Vascular Analysis syngo.CT Dual Energy syngo.CT Bone Reading **Note 1:** Detailed information about the subset of enabled syngo.CT functionalities are listed below.	enabled via software interface Recon&GO - Inline Results **varies methods contained in the available applications** syngo.CT Vascular Analysis syngo.CT Bone Reading syngo.CT MM Oncology syngo.CT Dual Energy syngo.via (incl. MM Reading ALPHA technology) syngo.CT Clinical Extensions syngo.CT LungCAD syngo.via RT Image Suite	enabled via stand alone workplace software installation **varies methods contained in the available applications** The user will operate the SOM/7-based scanner workplace and in addition have the possibility to use post-processing applications provided by a syngo.via-based system on the acquisition workplace.
Cybersecurity	IT Hardening	IT Hardening	IT Hardening
HD FoV	HD FoV 4.0	HD FoV 3.0	HD FoV 4.0
Standard technologies	• FAST Features • CARE Features • GO technology	• FAST Features • CARE Features • GO technology	• FAST Features • CARE Features
FAST Integrated Workflow for patient positioning	FAST Integrated Workflow steps supported: • FAST Isocentering • FAST Range • FAST Direction • FAST Topo • FAST Planning • FAST 3D Align • FAST 3D Camera	N/A	FAST Integrated Workflow steps supported: • FAST Isocentering • FAST Range • FAST Direction • FAST Topo • FAST Planning • FAST 3D Align • FAST 3D Camera

Properties software	*Subject Device*	*Primary Predicate Device*	*Predicate Device*
	SOMATOM X.cite	**SOMATOM go.Top**	**SOMATOM Force**
	(syngo CT VA30)	**(K173632)**	**(K190578)**
DirectDensity™	DirectDensity™ (including relative electron density and relative mass density)	N/A	DirectDensity™ (including relative electron density and relative mass density)
breath-hold technique	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations.	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations.	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations and DirectBreathhold™ (automated trigger supported)
Respiratory gating scan modes	Respiratory gated spiral and respiratory triggered sequence scan modes	Respiratory gated spiral scan mode	Respiratory gated spiral scan mode
Iterative Reconstruction Methods	• ADMIRE • iMAR	• SAFIRE • iMAR	• ADMIRE • SAFIRE • iMAR

Note 1: Detail information to support Recon&GO

The summary below provides detailed information about the subset of functionalities enabled by **Recon&GO – Advanced Reconstruction.**

Additional advanced reconstruction tools are provided through the advanced functionality of **Recon&GO**:

- Spectral Recon (Dual Energy Reconstruction)
- Inline Results DE SPP (Spectral Post-Processing)
- Inline Results DE Ranges (Parallel/Radial) / Inline DE

***Table S05**: Overview of Recon&GO advanced reconstruction tools supported by SOMATOM X.cite*

Recon&GO – Advanced Reconstruction	*510(k) information of the medical device software application that support same **reconstruction tools***
Recon&GO / Spectral Recon support image types - Virtual Unenhanced - Monoenergetic Plus	Reference Device K191468 - syngo.CT Dual Energy
Recon&GO / Inline Results DE SPP support - Dual Energy Spectral Post-Processing	Reference Device K191468 - syngo.CT Dual Energy
Recon&GO – Inline Results DE Ranges support the application classes: - Bone Removal/Direct Angio - Liver VNC - Monoenergetic + - Virtual Unenhanced - Lung Analysis - Gout - Kidney Stones*) - Bone Marrow - Brain Hemorrhage - Rho/Z - Liver Fat Map	Reference Device K191468 - syngo.CT Dual Energy
*) Kidney Stones is designed to support the visualization of the chemical composition of kidney stones and especially the differentiation between uric acid and non-uric acid stones. For full identification of the kidney stone additional clinical information should be considered such as patient history and urine testing. Only a well-trained radiologist can make the final diagnosis under consideration of all available information. The accuracy of identification is decreased in obese patients.	

Recon&GO – Advanced Reconstruction	*510(k) information of the medical device software application that support same* ***reconstruction tools***

The summary below in Table S06 provides detailed information about the subset of functionalities enabled by **Recon&GO – Post-Processing plug in functions.**

Table S06*: Overview of Recon&GO Inline Results post-processing methods supported by SOMATOM X.cite*

Enabled Recon&GO – Post-Processing plug in functions	510(k) information of the medical device software application that support same established post-processing methods
Heart Isolation, Coronary Tree, Vessel Ranges (LAD, RCA, CX), Cardiac Ranges	Reference Device K173637 – syngo.CT Coronary Analysis
Vascular ranges (Aorta, Carotis L Int., Carotic R Int., Runoff L, Runoff R) Inline Table removal, Inline Bone removal	Reference Device K173637 – syngo.CT Vascular Analysis
Radial Rib Ranges, Parallel Rib Ranges and Spine Range	Reference Device K123584 - syngo.CT Bone Reading

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 SOMATOM X.cite, is comparable to the predicate devices SOMATOM go.Top (K173632) and SOMATOM Force (K190578) in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

VII. Performance Data

Non-Clinical Testing

Non-clinical test (integration and functional) including phantom tests were conducted for the SOMATOM X.cite during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

The general purpose of each tests is to verify and validate the functionality of the subject device modifications.

Testing will cover all related subsystems that contribute to the device modifications. Test levels are defined. For each test level several test activities are performed. The test specification and acceptance criteria are related to the corresponding requirements. Various test activities are performed to specific modifications on different test levels to ensure safe and effective integration in the system. Three test levels are defined:

System Test (ST):

- Acceptance test (workflow and user manual test)
- Legal and Regulatory test

System Integration Test (SIT):

- System Integration Test (functional)
- Image Quality (IQ) test
- DICOM tests

Subsystem Integration Test (SSIT):

- Subsystem Integration Test
- DICOM tests

Tests are conducted for all software components developed in product development and for the complete product itself. Several activities are taken into account for this process, including creation of test specifications that relate to software/hardware requirements including tests to address risk mitigations that are identified, documented and traced by hazard keys.

Additional evaluation tests are performed as bench test to support the new device or device modification on Non-Clinical Performance Testing as listed in table S07 below.

Table S07: Non-Clinical Performance Testing

#	Feature/Non-Clinical Supportive Testing	Document Title	Testing Performed
01	kV and Filter independent CaScore	Evaluation of DirectDensity and Artificial120 kernels on Somaris/10 VA30	The test results show that performance of special kernel variants Artifical120 and eDDensity and mDDensity is similar or improved within the limits of accuracy of the test com-pared to the respective initial release versions. In conclusion, the features DirectDensity and Calcium Scoring at any kV have been enabled for the release SOMARIS/10 VA30.
02	Recon&GO - Spectral Recon	Detailed Description and Bench Test for the Feature "Spectral Recon"	Deviations between the already cleared image processing algorithms in Inline DE and the new technical realization "Spectral Recon" are extremely small and are not expected to have any impact on the diagnostic performance. Residual deviations are a consequence of rounding differences and slight differences in implementation.
03	TwinSpiral Dual Energy / TwinSpiral DE	Detailed Description and Bench Test for the Feature "TwinSpiral"	Based on these results it can be stated that the TwinSpiral Dual Energy CT scan mode provides CT-images of diagnostic quality, which are similar to conventional 120kV images in terms of CT-values and image noise at same radiation dose. The mixed images show a slight reduction in the iodine CT-value, but at the same time image noise at same dose is also lower. So in combination the iodine CNR at same radiation dose is comparable between Mixed images and 120kV images.
04	Flex 4D Spiral - Neuro/Body	Flex4D Spiral: Technical principals and demonstration of freely selectable scan ranges (*Somaris/10 VA30*)	Scan ranges with the new Flex4D Spiral feature can be freely selected within the limits mandated by the scan mode and protocol. The scanned volume was found to be in agreement with the planned scan range for a variety of different tested scan modes, scan lengths and scanners. Radiochromic film placed in the isocenter for a variety of scan ranges showed that the irradiated range markers displayed by the scanner acquisition software during the planning of the respective F4DS scans were in good agreement with the exposed area on the film.
05	DirectDensity	Evaluation of DirectDensity and Artificial120 kernels on Somaris/10 VA30	Evaluation of phantom images to demonstrate the subject device features ability to provide images that can be shown as relative mass density or relative electron density. The conducted test performed demonstrated the subject device's ability to show relative mass or relative electron density images.
06	HD FoV	HDFoV 4.0: Technical principles and phantom measurements evaluating HU accuracy and skin-line accuracy in the extended field of view (FoV) region (Som/10 VA30)	Phantom testing conducted to assess the subject device ability to provide visualization of anatomies outside the standard field of view and that the image quality standards for radiotherapy applications are met.
07	Contrast media protocol	Siemens Healthineers factory contrast protocols and comparison to approved drug labeling	Selected Factory Contrast Protocols are within the limits as prescribed by the approved labeling of Ultravist®". (No Ultravist protocol for coronary CTA)

#	Feature/Non-Clinical Supportive Testing	Document Title	Testing Performed
08	InjectorCoupling	Siemens Healthineers Injection Parameter Exchange Validation	Correctness of the contrast injection parameters transferred between the CT device and the supported injection devices has been verified.
09	FAST Integrated Workflow	FAST 3D Camera Evaluation	**FAST Isocentering**: Clinical data based software validation to assess accuracy of patient isocenter proposal for feature Conducted test for the subject device FAST Isocentering demonstrated that there was a lower isocenter deviation for the subject device in comparison to the predicate device. **FAST Range:** Based on manually triggerd camera images comparison and measurement of deviation of manual annotation of patient landmark and based on video stream images supporting the feature proposed patient landmark Conducted test demonstrated that a lower deviation for landmark boundaries for the subject device in comparison to the predicate device.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the SOMATOM X.cite in accordance with the following standards: 60601-2-44, and 60601-1-2. A list of recognized and general consensus standards considered for the subject devices is provided as **Table S08** and **Table S09** below.

Table S08: Recognized Consensus Standards

Date of Recognition	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
06/27/2016	12-300	NEMA	PS 3.1 - 3.20 (2016)	Digital Imaging And Communications In Medicine (DICOM) Set
03/14/2011	12-225	NEMA	XR-25	Computed Tomography Dose Check
01/27/2015	12-287	NEMA	XR-28 2013	Supplemental Requirements For User Information And System Function Related To Dose In CT
6/27/2016	5-40	ANSI AAMI ISO	14971:2007/(R)2010 (Corrected 4 October 2007)	Medical Devices - Applications Of Risk Management To Medical Devices
		ISO	14971 Second Edition 2007-03-01	Medical Devices - Applications Of Risk Management To Medical Devices
01/14/2019	13-79	IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical Device Software - Software Life Cycle Processes
07/09/2014	19-4	ANSI AAMI	ES60601-1:2005/(R)2012 And A1:2012,	C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
09/17/2018	19-8	ANSI AAMI IEC	60601-1-2:2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
7212/23/2016	5-114	ANSI AAMI IEC	62366-1:2015	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices

Table S08: Recognized Consensus Standards				
Date of Recognition	**Recognition Number**	**Standard Developing Organization**	**Standard Designation Number and Date**	**Title of Standard**
07/09/2014	12-273	IEC	60825-1 Edition 2.0 2007-03	Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
06/27/2016	12-302	IEC	60601-2-44 Edition 3.2: 2016	Medical Electrical Equipment - Part 2-44: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Computed Tomography
01/14/2014	12-269	IEC	60601-1-3 Edition 2.1 2013-04	Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment
06/27/2016	5-89	IEC	60601-1-6 Edition 3.1 2013-10	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
03/14/2011	12-226	IEC	61223-2-6 Second Edition 2006-11	Evaluation And Routine Testing In Medical Imaging Departments - Part 2-6: Constancy Tests - Imaging Performance Of Computed Tomography X-Ray Equipment
01/30/2014	12-270	IEC	61223-3-5 First Edition 2004-08	Evaluation And Routine Testing In Medical Imaging Departments - Part 3-5: Acceptance Tests - Imaging Performance Of Computed Tomography X-Ray Equipment [Including: Technical Corrigendum 1 (2006)]
06/07/2018	12-309	IEC	60601-2-28 Edition 3.0 2017-06	Medical Electrical Equipment - Part 2-28: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Tube Assemblies For Medical Diagnosis
06/27/2016	12-299	IEC	62563-1 Edition 1.1	Medical Electrical Equipment - Medical Image Display Systems - Part 1: Evaluation Methods

Table S09: General Use Consensus Standards			
Standard Developing Organization	**Standard Designation Number and Date**	**Title of Standard**	**How was Standard Used**
IEC	60601-1:2005+A1:2012	Medical electrical equipment - part 1: general requirements for basic safety and essential performance	Covered by ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 as part of EMC testing.
IEC/ISO	17050-1	Conformity Assessment – Supplier's declaration of conformity – Part 1: General requirements	Declaration of conformance to FDA recognized consensus standards.
IEC/ISO	17050-2	Conformity assessment – Supplier's declaration of	General consensus standards not currently recognized by FDA.

Table S09: General Use Consensus Standards			
Standard Developing Organization	**Standard Designation Number and Date**	**Title of Standard**	**How was Standard Used**
		conformity – Part 2: Supporting documentation.	

A list of applicable guidance documents considered for this submission is provided as **Table S10** below.

Table S10	FDA Guidance Document and Effective Date
1.	Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k)** Document issued on October 2, 2017
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s** Document issued on February 21, 2019
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff** Document issued on August 12, 2005
4.	Guidance for Industry and FDA Staff: **Deciding when to submit a 510(k) for a change to an existing device.** Document issued on October 25, 2017
5.	Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** Document Issued on July 28, 2014
6.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices** Document issued on May 11, 2005
7.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices** Document issued on September 9, 1999
8.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices**. Document issued February 3, 2016
9.	Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications.** Document issued on November 28, 2017
10.	Guidance for Industry and FDA Staff: **Content of Premarket Submissions for Management of Cybersecurity in Medical devices.** Document issued on October 2, 2014
11.	Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices** Document issued on July 11, 2016
12.	Guidance for Industry and Food Drug Administration Staff: **Design considerations and Pre-Market Submission recommendations for Interoperable Medical devices** Document Issued on September 6, 2017
13.	Guidance for Industry and Food Drug Administration Staff: **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices** Document issued on September 14, 2018

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 claims of substantial equivalence.

Siemens 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**.**

Additionally, Siemens conforms to the requirements for Radio Frequency Wireless Technology as defined in FDA guidance document "Radio Frequency Wireless Technology in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, issued on August 14, 2013" by adhering to the EMC and risk based verification and validation requirements in design, testing, and labeling of the wireless remote control components of the subject devices.

The Radio Frequency Wireless Technology of the optional Remote Scan Control and supporting Control Device tablet for Scan&GO complies to 47 CFR part 15 subpart c – Intentional Radiators. All Radio device labels will show an FCC ID code to show compliance. Shielding requirement applicable to the CT Scanners and respective Scatter Radiation diagrams for typical room installations are provided in the User Documentation and Planning Guide of the intended Scanners in accordance to IEC60601-2-44.

Wireless Coexistence Testing
Siemens has considered several measures to address wireless coexistence by design to ensure the safe operation of the wireless components in combination with the applicable system supported functionality. Wireless technology in the system setup to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules has been considered. According to FDA guidance 'Radio Frequency Wireless Technology in Medical Devices" Siemens has addressed the safety, effectiveness, and high likelihood of coexistence with other devices of this technology in our product design by our Risk Management Process, Failure Mode and Effects Analysis (FMEA) Process, and Requirement Engineering Process. As part of the risk management process, hazardous situations associated with the Scan&GO and its connection to the host system via Wi-Fi were addressed as part of the Risk Management process.

Testing for co-existence considered for following scenarios:

- Co-Channel Testing
- Adjacent Channel Testing
- RF Interference Testing
- Separation Distance/Location Testing

Scan&GO is designed to allow dynamic frequency selection and transmission power control by default in accordance with IEEE 802.11h, Wireless LAN. Adjacent channel testing is addressed by the fact that Scan&GO does not support shared medium access to Siemens Wi-Fi network. RF interference was tested by successfully ensuring that wireless communications were actively transmitting in situations where possible interference may exist. Recommended distance and router locations requirements are documented in the user documentation.

Customer Use Testing
The following clinical use testing was conducted to demonstrate Scan&GO's performance in the intended clinical environment:

- ***Internal Clinical Use Test***: The CT scanner customer environment is simulated in Siemens Test Cabins. For such a test, customers with clinical expertise are typically invited to perform tests.
- ***External Clinical Use Test:*** The CT scanner is tested in the environment of the clinic/hospital. Typically we perform these tests with selected customer before rollout of the CT scanner.

All test performed meet the pre-determined acceptance criteria and demonstrate that Scan&GO is safe and effective for the intended use. Multiple tablet for visualization purpose, using same Scan&GO installation and feature configuration does not change the intended use.

Additional Supportive Data
The National Lung Screening Trial (NLST), sponsored by the National Cancer Institute, is used to support the additional lung cancer screening Indications for Use. The study was a randomized trial of screening with the use of low-dose CT compared to chest radiography to determine whether screening with low-dose CT could reduce mortality from lung cancer. The study start date was August, 2002 and the completion date was October, 2010. The interpretation task with CT for this study was to detect lung nodules of 4mm diameter or greater.

Summary
The features described in this premarket notification are supported with verification and validation testing, dosimetry and imaging performance, and analysis of phantom images to assess device and feature performance during product development. The risk analysis was completed and risk control implemented to mitigate identified hazards. The test results show that all of the software specifications have met the acceptance criteria. Verification and validation testing of the device was found acceptable to support the claim of substantial equivalence.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a system related Risk analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. In order to minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

VIII. Conclusions

The predicate devices were cleared based on the results of non-clinical testing including verification and validation, phantom tests, and supportive literature. The subject device is also tested using the same methods as used for the predicate devices. The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrates that the subject device SOMATOM X.cite should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM X.cite performs comparably to the predicate devices currently marketed for the same intended use. Since all predicate devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM X.cite testing supports substantial equivalence.