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

April 1, 2020

Re: K200524
Trade/Device Name: SOMATOM X.cite and SOMATOM go.Platform CT Scanners including: SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go. Open Pro, Scan&GO
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: February 28, 2020
Received: March 2, 2020

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)*

K200524

Device Name

SOMATOM X.cite and SOMATOM Go Platform CT Scanners including: SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim and SOMATOM go.Open Pro , Scan&Go

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)*

K200524

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.

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K200524

510(K) SUMMARY
FOR
SOMATOM GO. PLATFORM & SOMATOM X.CITE CT SCANNER SYSTEMS – SOFTWARE VERSION SOMARIS/10 syngo CT VA30 (Update)

Submitted by:
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932
Date Prepared: February 28, 2020

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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II. Device Name and Classification

Product Name:	SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite
Trade Name:	SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, 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 X.cite, Scan&GO
510(k) Number:	K191891
Clearance Date:	November 06, 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

Reference Device:

Trade Name:	SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, Scan&GO
510(k) Number:	K192061
Clearance Date:	November 21, 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:	All predicate device recalls have been considered in the subject device design.

Note: K192061 was a bundle submission with various Siemens CT Scanner Systems, including SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro and Scan&GO software. In this submission, the predicate devices SOMATOM go.Top and Scan&GO are applicable, to demonstrate substantial equivalence of technological characteristics.

IV. Device Description

Siemens intends to update software version, SOMARIS/10 syngo CT VA30 (Update) for Siemens SOMATOM Computed Tomography (CT) Scanner Systems with mobile workflow and 3D Camera options.
This update includes support of additional hardware for the go. platform and includes reuse of optional postprocessing applications for Recon&GO for all scanners subject of this submission.

The SOMATOM CT Scanner Systems that support the same software platform update include:

- SOMATOM go.Up
- SOMATOM go.Now
- SOMATOM go.Top
- SOMATOM go.All
- SOMATOM go.Sim
- SOMATOM go.Open Pro
- SOMATOM X.cite
- Scan&GO Mobile Medical Application (optional mobile workflow component)

The subject device SOMATOM go. platform and SOMATOM X.cite with SOMARIS/10 syngo CT VA30 (update) are Computed Tomography X-ray Systems which feature one continuously rotating tube-detector system and function according to the fan beam principle. The SOMATOM go. platform and SOMATOM X.cite with software SOMARIS/10 syngo CT VA30 (update) produces CT images in DICOM format. These images can be used by trained staff for post-processing applications commercially distributed by Siemens Healthcare and other vendors. These images 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 and SOMATOM go. platform CT scanners. Scan&GO can be operated on a Siemens provided tablet or personal computer 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 or personal computer with WiFi connection 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”)
- Control function for RTP Laser systems
- 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 go. platform and SOMATOM X.cite, syngo CT VA30 (update) (SOMARIS/10 syngo CT VA30 (update)), 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 (update) is designed to support a software plugin interface to reuse a subset of stand-alone, cleared processing software

applications. Software update version syngo CT VA30 (update) (SOMARIS/10 syngo CT VA30 (update)) shall support additional software features and hardware options, which was cleared for the primary predicate device in K191891, 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 go. platform and SOMATOM X.cite will support the following modifications/further developments in comparison to the predicate devices:

1) New/Modified Hardware

- **Table S5-01**: Overview of Hardware modifications

2) Software version SOMARIS/10 syngo CT VA30 (update)

- **Table S5-02**: Overview Software modifications

The configuration table and comparison table 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 or cleared Siemens stand alone software applications. This feature will be supported for the subject device with software version SOMARIS/10 syngo CT VA30 (update) and is substantial equivalent from it's cleared version.

Table S5-01: Overview of ***Hardware Modifications*** *in comparison to the corresponding predicate devices*

	CT Scanner Systems with SOMARIS/10 syngo CT VA30 (update)	*Subject Devices*	*Subject Devices*	*Subject Devices*	*Subject Devices*	*Subject Devices*	*Subject Devices*
#	**hardware properties**	**SOMATOM go.Now**	**SOMATOM go.Up**	**SOMATOM go.All/ go.Top**	**SOMATOM go.Sim / go.Open Pro**	**SOMATOM X.cite**	**Scan&GO**
1	3D Camera	N/A	Enabled	Enabled	Enabled	Unmodified	N/A
2	Optional hardware for Scan&GO to support inroom monitor.	Unmodified	Unmodified	Unmodified	Unmodified	Unmodified	Modified

Table S5-02: *Overview* ***Software modifications*** *of SOMATOM go. platform and SOMATOM X.cite with syngo CT VA30 (update) in comparison to the corresponding predicate devices*

	CT Scanner Systems with SOMARIS/10 syngo CT VA30 (update)	*Subject Devices*	*Subject Devices*	*Subject Devices*	*Subject Devices*	*Subject Devices*	*Subject Devices*
	Software properties	**SOMATOM go.Now**	**SOMATOM go.Up**	**SOMATOM go.All/ go.Top**	**SOMATOM go.Sim/ go.Open Pro**	**SOMATOM X.cite**	**Scan&GO**
1	Recon&GO – Inline Results • LungCAD • Anatomical Ranges	Unmodified	Unmodified	Unmodified	Enabled	Enabled	N/A
2	Recon&GO – Inline Results • RT Automatic Contouring (DirectORGANS)	N/A	N/A	N/A	Enabled	Enabled	N/A
3	Recon&GO – Inline Results • CaScoring	N/A	N/A	Enabled	Enabled	Enabled	N/A
4	Contrast media protocol (additional protocol for coronary CTA)	N/A	N/A	Modified	Modified	Modified	N/A
5	FAST Integrated Workflow (including FAST 3D Camera)	N/A	Enabled	Enabled	Enabled	Unmodified	Unmodified

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. Software version SOMARIS/10 syngo CT VA30 (update) will be offered as an optional upgrade for the existing SOMATOM CT go.platform Systems and SOMATOM X.cite.

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:
The 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 subject devices (SOMATOM go. platform scanners, SOMATOM X.cite scanners and optional Scan&GO mobile workflow software application) provide the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software features of the SOMATOM go. platform and SOMATOM X.cite have been modified in comparison to the predicate devices to support additional hardware options and to reuse a subset of cleared postprocessing algorithms. The subject devices CT scanner hardware is unmodified as cleared with K192061 and K191891. The hardware modification in combination with the subject devices support a mobile workflow option with personal computer configuration and 3D Camera workflow for patient positioning.

Software version SOMARIS/10 syngo CT VA30 (update) supports software features that are designed as a software platform update including Recon&GO Inline Result technologies which provide interfaces to directly access a subset of optional post processing applications and are designed to enhance the user workflow.

The intended use and fundamental scientific technology for the SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro and 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

- Chronon, 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 go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite and the primary predicate device SOMATOM X.cite cleared in K191891 and the predicate device SOMATOM go.Top cleared in K192061:

- Software version SOMARIS/10 syngo CT VA30 (update) (enable additional hardware/software options)
- Mobile workflow include Scan&GO installation on personal computer
- Various additional post processing software plug-in options for Recon&GO Inline Results
- Optional advanced CARE examination including new protocol for contrast media

The following technological differences exist between the subject device Scan&GO and the predicate device Scan&GO cleared in K191891:

- Optional hardware support for personal computer configuration

A summary of the differences between the subject device CT scanner configurations is provided as **Table S5-03 and Table S5-04** below.

The tabular summary of the comparable hardware properties between the subject devices SOMATOM go. platform CT Scanner Systems with software version SOMARIS/10 syngo CT VA30 (update) and the predicate device SOMATOM X.cite are listed in **Table S5-03** below (modifications are in gray shaded sections).

There are no hardware changes for subject device SOMATOM X.cite in comparison to the predicate device SOMATOM X.cite cleared in K191891.

Table S5-03: *SOMATOM go. platform comparable hardware properties*

Hardware Property	**SOMATOM go. platform - Device Comparison** (Single Source Systems)						
	Subject Device				**Subject Device**		**Predicate**
	SOMATOM go.Now	**SOMATOM go.Up**	**SOMATOM go.All**	**SOMATOM go.Top**	**SOMATOM go.Sim**	**SOMATOM go.Open Pro**	**SOMATOM X.cite K191891**
Scanner	whole body X-ray computed tomography scanner						
Generator max. power	32 kW	32 kW	75 kW	75 kW	75 kW	75 kW	105 kW
Detector technology	Stellar	Stellar	Stellar	Stellar	Stellar	Stellar	Stellar
Detector volumen coverage	11.2 mm	22.4 mm	22.4 mm	38.4 mm	19.2 mm	38.4 mm	38.4 mm
Detector physical rows	16	32	32	64	32	64	64
Detector slice width	0.7 mm	0.7 mm	0.7 mm	0.6 mm	0.6 mm	0.6 mm	0.6 mm
Detector DAS channel No.	768	768	768	840	920	920	840
Detector image slices	32	64	64	128	64	128	128
Tube Technologie	Chronon	Chronon	Athlon	Athlon	Athlon	Athlon	Vectron
Tube kV steps	(in 20kV steps) 80 kV to 130kV		(in 10kV steps) 70 kV to 140 kV				(in 10kV steps) 70 kV to 150 kV
Tube max. current	400 mA	400 mA	825 mA	825 mA	825 mA	825 mA	1200 mA
Tube tube focus	0.8 x 0.4 0.8 x 0.7	0.8 x 0.4 0.8 x 0.7	1.0 x 1.2 0.8 x 0.8	1.0 x 1.2 0.8 x 0.8	1.0 x 1.2 0.8 x 0.8	1.0 x 1.2 0.8 x 0.8	0.6 x 0.7 0.8 x 1.1
Tube heat capacity	3.5 MHU	3.5 MHU	6 MHU	6 MHU	6 MHU	6 MHU	>30 MHU
Gantry bore size	70 cm	70 cm	70 cm	70 cm	85 cm	85 cm	82 cm
Gantry FoV	50 cm	50 cm	50 cm	50 cm	60 cm	60 cm	50 cm
Gantry rotation time (sec)	0.8, 1.0, 1.5		0.33, 0.5, 1.0		0.35, 0.5, 1.0		0.3, 0.5, 1.0
Gantry Tilt [degrees]	N/A	+/-25	+/-25	+/-25	+/-25	+/-25	+/-25
Patient Table type	Vector: 1.250 m Vario 1 and Vario RT: 1.600 m with table extension	Vario 1 (1.600 m, Vario 2 (2.000m and Vario RT: 1.600 m with table extension			Vario 2 (2.000m and Vario RT: 1.600 m with table extension		Vario RT: 1.600 m, Vario 2: 2.000 m
Max. Scan length Topogram	1680 mm	1680 mm 2080 mm	1680 mm 2080 mm	1680 mm 2080 mm	1680 mm 2080 mm	1680 mm 2080 mm	1680 mm 2080 mm
Max. Scan length Image acquisition	1600 mm	1600 mm, 2000 mm	1600 mm, 2000 mm	1600 mm, 2000 mm	1600 mm, 2000 mm	1600 mm, 2000 mm	1600 mm, 2000 mm
Spectral filtration option	Tin Filter supported	Tin Filter supported	Tin Filter supported	Combined Split Filter/Tin Filter	Tin Filter supported	Combined Split Filter/Tin Filter	Combined Split Filter / Tin Filter supported, plus extra Tin Filter
3D Camera for patient positioning	N/A	supported					supported
High Power 70	N/A	N/A	825 mA (@ 70 kV)	825 mA (@ 70 kV)	825 mA (@ 70 kV)	825 mA (@ 70 kV)	1200 mA (@ 70 kV)
High Power 80	N/A	N/A	825 mA (@ 80 kV)	825 mA (@ 80 kV)	825 mA (@ 80 kV)	825 mA (@ 80 kV)	1200 mA (@ 80 kV)

The tabular summary of the comparable **software properties** between the subject devices with software version SOMARIS/10 syngo CT VA30 (update) and the predicate devices are listed in **Table S5-04** below (modifications are in gray shaded sections).

Table S5-04: *SOMATOM go. platform and SOMATOM X.cite comparable software properties*

Properties software	***Subject Device***	***Predicate Device***	***Predicate Device***
	• **SOMATOM go.Now,** • **SOMATOM go.Up,** • **SOMATOM go.All,** • **SOMATOM go.Top,** • **SOMATOM go.Sim,** • **SOMATOM go.Open Pro,** • **SOMATOM X.cite**	• **SOMATOM X.cite**	• **SOMATOM go.Top**
	(syngo CT VA30 (update))	**(K191891)**	**(K192061)**
Operating System	Windows based SOMARIS/10 syngo CT VA30 (update) (with additional software options)	Windows based SOMARIS/10 syngo CT VA30 (update)A	Windows based SOMARIS/10 syngo CT VA30 (update)
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	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 (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • TwinBeam DE • TwinSpiral DE • Flex 4D Spiral	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 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
Recon&GO – Advanced Reconstruction.	Advanced reconstruction tools supported: - Spectral Recon (Dual Energy Reconstruction) - Inline Results DE SPP (Spectral Post-Processing) - Inline Results DE Ranges (Parallel/Radial) / Inline DE	Advanced reconstruction tools supported: - Spectral Recon (Dual Energy Reconstruction) - Inline Results DE SPP (Spectral Post-Processing) - Inline Results DE Ranges (Parallel/Radial) / Inline DE	Advanced reconstruction tools provided to supported: - Spectral Recon (Dual Energy Reconstruction) - Inline Results DE SPP (Spectral Post-Processing) - Inline Results DE Ranges (Parallel/Radial) / Inline DE
Post-Processing plug in functions Enabled via software	- Heart Isolation, - Coronary Tree, - Vessel Ranges (LAD, RCA, CX), - Cardiac Ranges	- Heart Isolation, - Coronary Tree, - Vessel Ranges (LAD, RCA, CX), - Cardiac Ranges	- Heart Isolation, - Coronary Tree, - Vessel Ranges (LAD, RCA, CX), - Cardiac Ranges

Properties software	***Subject Device***	***Predicate Device***	***Predicate Device***
	• **SOMATOM go.Now,** • **SOMATOM go.Up,** • **SOMATOM go.All,** • **SOMATOM go.Top,** • **SOMATOM go.Sim,** • **SOMATOM go.Open Pro,** • **SOMATOM X.cite**	• **SOMATOM X.cite**	• **SOMATOM go.Top**
	(syngo CT VA30 (update))	**(K191891)**	**(K192061)**
interface **Recon&GO - Inline Results** varies methods of cleared software applications **Note 1:** Detailed informations about the subset of enabled syngo functionalities are listed below.	- Vascular ranges (Aorta, Carotis L Int., Carotic R Int., Runoff L, Runoff R) - Inline Table removal - Inline Bone removal	- Vascular ranges (Aorta, Carotis L Int., Carotic R Int., Runoff L, Runoff R) - Inline Table removal - Inline Bone removal	- Vascular ranges (Aorta, Carotis L Int., Carotic R Int., Runoff L, Runoff R) - Inline Table removal - Inline Bone removal
	- LungCAD - Anatomical ranges (Parallel/Radial)	N/A	- LungCAD - Anatomical ranges (Parallel/Radial)
	- Radial Rib Ranges - Parallel Rib Ranges - Spine Range	- Radial Rib Ranges - Parallel Rib Ranges - Spine Range	- Radial Rib Ranges - Parallel Rib Ranges - Spine Range
	- 3D and 4D image visualization, manipulation and manual contouring tools for preparation and response assessment of radiotherapy treatment.	- 3D and 4D image visualization, manipulation and manual contouring tools for preparation and response assessment of radiotherapy treatment.	- 3D and 4D image visualization, manipulation and manual contouring tools for preparation and response assessment of radiotherapy treatment.
	- CaScoring (Not supported by SOMATOM go.Now and go.Up)	- Automated CaScoring function is supported via stand alone software application syngo.CT CaScoring (K192763)	- Automated CaScoring function is supported via stand alone software application syngo.CT CaScoring
	- RT Automatic Contouring (DirectORGANS) (Not supported by SOMATOM go.Now, go.Up, go.All, go.Top)	- Automatic Contouring function is supported via stand alone software application syngo.via RT Image Suite (K192065)	- Automatic Contouring function is supported via stand alone software application syngo.via RT Image Suite (K192065)
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
DirectDensity™	DirectDensity™ (including relative electron density and relative mass density)	DirectDensity™ (including relative electron density and relative mass density)	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.
Respiratory gating scan modes	Respiratory gated spiral and respiratory triggered sequence scan modes	Respiratory gated spiral and respiratory triggered sequence scan modes	Respiratory gated spiral and respiratory triggered sequence scan modes
Iterative Reconstruction Methods	• SAFIRE • iMAR • ADMIRE (only for X.cite)	• SAFIRE • iMAR • ADMIRE	• SAFIRE • iMAR

Note 1: Detail information to support Recon&GO

The summary below in Table S05 provides detailed information about the subset of functionalities enabled by **Recon&GO – Post-Processing plug in functions.**

***Table S5-05**: Overview of Recon&GO Inline Results post-processing methods supported by subject devices supporting syngo CT VA30 (update)*

Supported post-processing plug in functions	510(k) information of the medical device software application that support **same** established post-processing methods
Recon&GO – Inline Results - Heart Isolation, - Coronary Tree, - Vessel Ranges (LAD, RCA, CX), - Cardiac Ranges	Primary Predicate Device: K191891 – SOMATOM X.cite Reference Device: K173637 – syngo.CT Coronary Analysis
Recon&GO – Inline Results - Vascular ranges (Aorta, Carotis L Int., Carotic R Int., Runoff L, Runoff R) - Inline Table removal - Inline Bone removal	Primary Predicate Device: K191891 – SOMATOM X.cite Reference Device: K173637 – syngo.CT Vascular Analysis
Recon&GO – Inline Results - LungCAD	Predicate Device: K192061 – SOMATOM go.Top Reference Device: K143196 – syngo.CT LungCAD
Recon&GO – Inline Results - Anatomical ranges (Parallel/Radial)	Predicate Device: K192061 – SOMATOM go.Top Reference Device: K191040 - syngo.via
Recon&GO – Inline Results - Radial Rib Ranges - Parallel Rib Ranges - Spine Range	Primary Predicate Device: K191891 – SOMATOM X.cite Reference Device: K123584 - syngo.CT Bone Reading
Recon&GO – Inline Results - 3D and 4D image visualization, manipulation and manual contouring tools for preparation and response assessment of radiotherapy treatment.	Primary Predicate Device: K191891 – SOMATOM X.cite Reference Device: K192065 – syngo.via RT Image Suite
Recon&GO – Inline Results - CaScoring (Not supported by SOMATOM go.Now and go.Up)	Reference Device: K192763 – syngo.CT CaScoring
Recon&GO – Inline Results - RT Automatic Contouring (DirectORGANS) (Supported by SOMATOM go.Sim, SOMATOM go.Open Pro and SOMATOM X.cite)	Reference Device: K192065 – syngo.via RT Image Suite

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 devices, the SOMATOM CT Scanner Systems, 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

Non-clinical test (integration and functional) including phantom tests were conducted for the SOMATOM go. platform CT Scanner Systems and 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 Validation test:

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

System Verification test:

- System Integration Test (functional)
- Functionality verification
- Image Quality (IQ) Evaluation

Tests are conducted for all software components developed in product development and for the complete product itself. Several activities are considered 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 tests to support the new device or device modification on Non-Clinical Performance Testing as listed in table **S5-06** below.

Table S5-06: *Non-Clinical Performance Testing*

#	Feature/Non-Clinical Supportive Testing	Document Title	Testing Performed
01	FAST Integrated Workflow	FAST 3D Camera Evaluation	**FAST Isocentering**: Clinical data based software validation to assess accuracy of patient isocenter proposal for feature. Conducted tests 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 triggered 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 a lower deviation for landmark boundaries for the subject device in comparison to the predicate device.
02	Contrast media protocol	Siemens Healthineers factory contrast protocols and comparison to approved drug labeling	All factory contrast protocols are within the limits as prescribed by the approved labeling of Ultravist® or Visipaque®. (including coronary CTA contrast protocol)
03	Scan&GO supported hardware	Bench test: Scan&GO Mobile Medical Application Software (supporting	With software version VA30 the additional hardware support the information shown on the in-room monitor in the same way as it is shown on the tablets.

#	Feature/Non-Clinical Supportive Testing	Document Title	Testing Performed
		optional PC and Monitor hardware)	

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the subject device SOMATOM CT Scanner Systems 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 S5-07** and **Table S5-08** below.

Table S5-07: *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
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

Date of Recognition	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
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 S5-08: *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 conformity – Part 2: Supporting documentation.	General consensus standards not currently recognized by FDA.

A list of applicable guidance documents considered for this submission is provided as **Table S5-09** below.

Table S5-09: 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: **The Special 510(k) Program - 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. 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 tests performed meet the pre-determined acceptance criteria and demonstrate that Scan&GO is safe and effective for the intended use. Multiple tablets for visualisation purpose, using the 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 devices are also tested using the same test methods and workflows 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 SOMATOM go. platform and SOMATOM X.cite should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM go. platform and SOMATOM X.cite with described modifications performs comparably to the predicate devices currently marketed for the same intended use. Since the subject and predicate devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM go. platform and SOMATOM X.cite testing supports a finding of substantial equivalence.

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