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

August 27, 2021

Re: K211373
Trade/Device Name: SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite SOMATOM X.ceed, Scan&GO Software

Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: April 30, 2021
Received: May 4, 2021

Dear Alaine Medio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211373

Device Name
SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite, SOMATOM X.ceed, Scan&GO Software

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.

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510(K) SUMMARY

FOR

SOMATOM GO. PLATFORM AND SOMATOM X. PLATFORM

CT SCANNER SYSTEMS

– SOFTWARE VERSION SOMARIS/10 syngo CT VA40

Submitted by:
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932
Date Prepared: February 21, 2021

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 Names:	SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite, SOMATOM X.ceed, Scan&GO Software
Trade Names:	SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite, SOMATOM X.ceed, Scan&GO Software
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

III. Predicate Device

Primary Predicate Device:

Trade Names:	SOMATOM X.cite, Scan&GO
510(k) Number:	K200524
Clearance Date:	April 01, 2020
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.

Reference Device:

Trade Name:	SOMATOM go.Top, SOMATOM go.Open Pro
510(k) Number:	K200524
Clearance Date:	April 01, 2020
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: K200524 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, SOMATOM X.cite and Scan&GO software.

Reference Device:

Trade Name:	SOMATOM Force
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:	All predicate device recalls have been considered in the subject device design.

In this submission, the primary predicate device SOMATOM X.cite including Scan&GO and the reference devices SOMATOM go.Top and SOMATOM Force are being used, to demonstrate substantial equivalence of technological characteristics.

IV. Device Description

Siemens intends to update software version, SOMARIS/10 syngo CT VA40 for Siemens SOMATOM Computed Tomography (CT) Scanner Systems with unmodified mobile workflow options.
This update also includes optional hardware for CT guided intervention workflow for the X. platform supporting CT Scanner Systems.

SOMATOM go.Platform is comprised of the following 6 CT scanners and optional mobile workflow:

- SOMATOM go.Up
- SOMATOM go.Now
- SOMATOM go.Top
- SOMATOM go.All
- SOMATOM go.Sim
- SOMATOM go.Open Pro
- Scan&GO Software (optional mobile workflow component)

SOMATOM X. platform is comprised of the following 2 CT scanners and optional mobile workflow:

- SOMATOM X.cite
- SOMATOM X.ceed (new CT Scanner Model)
- Scan&GO Software (optional mobile workflow component)

The subject device SOMATOM go. platform and SOMATOM X. platform with SOMARIS/10 syngo CT VA40 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. platform with software SOMARIS/10 syngo CT VA40 produces CT images in DICOM format. These images can be used by trained staff for post-processing applications commercially distributed by Siemens Medical Solutions USA, Inc. 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 subject device platform CT scanners. Scan&GO can be operated on a Siemens provided various tablet hardware 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 Wi-Fi 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 mood light 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, syngo CT VA40 (SOMARIS/10 syngo CT VA40), is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The software platform provides a software plugin interface that allows for the use of specific commercially available post processing software algorithms in an unmodified form from the cleared stand-alone post processing version.

Software version syngo CT VA40 (SOMARIS/10 syngo CT VA40) is an update to software version syngo CT VA30A (SOMARIS/10 syngo CT VA30) which was cleared for the primary predicate devices in K200524 and supports the same plugin interfaces for the optional Scan&GO mobile workflow and integration of post-processing tasks as the predicate devices.

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.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject devices (SOMATOM go. platform scanners, SOMATOM X. platform 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 new syngo CT VA40 software supports the software update of existing CT Scanner Systems SOMATOM go. platform and SOMATOM X.cite. In addition, the software version syngo CT VA40 support the new CT scanner model SOMATOM X.ceed.

The new syngo CT VA40 software reuses all unmodified software features of the legacy software syngo CT VA30 cleared for the primary predicate device SOMATOM X.cite in K200524 and described below in the section “Unmodified Features used in the Subject Devices”.

The SOMATOM X. platform also supports an optional laser component for a modified CT guided intervention workflow.

As with the primary predicate device SOMATOM X.cite, the subject devices CT Scanner Systems in combination with Scan&GO support an optional mobile workflow. This workflow has also been modified to enable a new tablet hardware iPad with iPad OS operating software that support subject device Scan&GO mobile medical application software installation.

SOMARIS/10 syngo CT VA40 is designed to reuse hardware independent extended functionalities and GO technologies provided by Siemens cleared commercially available software applications. The intended use and fundamental scientific technology for these independent software applications are unchanged from their cleared and released software when incorporated for use on the SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite and SOMATOM X.ceed CT scanner systems.

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 CT Guided Interventional 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 and Interfaces

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, SOMATOM X.ceed and the primary predicate device SOMATOM X.cite and the reference device SOMATOM go.Top cleared in K200524:

- Software version SOMARIS/10 syngo CT VA40
- Additional options for Inline Results and GO technologies
- CT guided intervention – modified hardware and software application
- Precision Matrix function

The following technological differences exist between the subject device Scan&GO and the predicate device Scan&GO cleared in K200524:

- Software version SOMARIS/10 syngo CT VA40
- iPad hardware to support mobile workflow options
- CT guided intervention – modified software application

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

1) **New/Modified Hardware**
    - **Table S5-02**: Overview of hardware modifications

2) **Software version SOMARIS/10 syngo CT VA40**
    - **Table S5-03**: 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:

Table S5-01: Overview term definition

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 predicate / reference devices
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 VA40 and is substantially equivalent compared to the cleared version.

Table S5-02: Overview of hardware modifications in comparison to the corresponding predicate devices

	CT Scanner Systems with SOMARIS/10 syngo CT VA40	Subject Devices					
	Hardware properties	SOMATOM go.Now/ go.Up	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.Sim/ go.Open Pro	SOMATOM X.cite	SOMATOM X.ceed
01	CT guided intervention: myNeedle Laser (part of myNeedle Companion)	N/A	N/A	N/A	N/A	new	new
02	Tablet hardware for Scan&GO - iPad	modified	modified	modified	modified	modified	modified
03	CT Detector - Fan geometry	unmodified	unmodified	unmodified	unmodified	unmodified	Modified
04	UHR imaging-Ultra High Resolution for sub millimeter anatomical structures	N/A	N/A	N/A	N/A	N/A	enabled[1]
05	Patient Table Configuration	unmodified	unmodified	unmodified	unmodified	modified	modified

[1]Note 1: This feature is cleared in K190578 – SOMATOM Force with SOMARIS/7 and enabled on SOMARIS/10 for the supporting subject devices.

Table S5-03: Overview software modifications of SOMATOM go. platform and SOMATOM X. platform with syngo CT VA40

		Subject Devices	Subject Device	Subject Device	Subject Devices	Subject Device	Subject Device
	Software properties	SOMATOM go.Now/ go.Up	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.Sim/ go.Open Pro	SOMATOM X.cite	SOMATOM X.ceed
01	Precision Matrix (1024^2) (large image matrices)	N/A	N/A	enabled[1]	enabled[1]	enabled[1]	enabled[1]
02	CT guided intervention: myNeedle Guide (part of myNeedle Companion)	modified	modified	modified	modified	modified	modified
03	Flex 4D Spiral – Neuro / Body	N/A	unmodified	unmodified	unmodified	modified	modified

		Subject Devices	Subject Device	Subject Device	Subject Devices	Subject Device	Subject Device
	Software properties	SOMATOM go.Now/ go.Up	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.Sim/ go.Open Pro	SOMATOM X.cite	SOMATOM X.ceed
04	CT projection read-out frequency - 8kHz imaging	N/A	N/A	N/A	N/A	N/A	modified
05	Imaging – Cardio BestPhase	N/A	unmodified	unmodified	unmodified	unmodified	enabled[2]
06	ADMIRE	N/A	enabled[2]	enabled[2]	N/A	unmodified	enabled[2]
07	UHR imaging- Ultra High Resolution for sub millimeter anatomical structures	N/A	N/A	N/A	N/A	N/A	enabled[1]
08	Cardiac CT imaging - Motion artifact reduced ECG-gated imaging	N/A	unmodified	unmodified	unmodified	unmodified	modified
09	Motion artifact reduced non-gated imaging	N/A	unmodified	unmodified	unmodified	unmodified	modified
10	myExam Satellite	N/A	N/A	modified	modified	modified	modified

[1]Note 1: This feature is cleared in K190578 – SOMATOM Force with SOMARIS/7 and enabled on SOMARIS/10 for the supporting subject devices.

[2]Note 2: This feature is cleared in K200524 – SOMATOM X.cite with SOMARIS/10 and enabled for the supporting subject devices.

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 VA40 will be offered as an optional upgrade for the existing SOMATOM CT go. platform Systems and SOMATOM X.cite.

A tabular summary of the comparable hardware properties between the subject devices SOMATOM go. platform and SOMATOM X. platform CT Scanner Systems with software version syngo CT VA40 and the predicate device are listed in **Table S5-04** and **Table S5-05** below (modifications are in gray shaded sections).

Table S5-04: SOMATOM go. platform comparable hardware properties

Hardware Property	**SOMATOM go. platform - Device Comparison** (Single Source Systems)						
	Subject Device						**Primary Predicate**
	SOMATOM go.Now	**SOMATOM go.Up**	**SOMATOM go.All**	**SOMATOM go.Top**	**SOMATOM go.Sim**	**SOMATOM go.Open Pro**	**SOMATOM X.cite (K200524)**
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 Infinity
Detector volume 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 Technology	Chronon	Chronon	Athlon	Athlon	Athlon	Athlon	Vectron
Tube kV steps	80kV, 110kV,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 Scan 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: 1250 mm Vario 1/Vario RT: 1600 mm with table extension	Vario 1 (1600 mm, Vario 2 (2000m and Vario RT: 1600 mm with table extension			Vario 2 (2000mm and Vario RT: 1600 mm with table extension		Vario RT: 1600 mm with table extension Vario 2: 2000 mm with table extension
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	N/A	supported					supported
High Power 70 (@70kV)	N/A	N/A	825 mA	825 mA	825 mA	825 mA	1200 mA
High Power 80 (@80kV)	N/A	N/A	825 mA	825 mA	825 mA	825 mA	1200 mA
Respiratory Gating sensor	Anzai - AZ, Varian - RGSC				Anzai - AZ, Varian – RGSC		Anzai - AZ, Varian – RGSC

Table S5-05: SOMATOM X. platform comparable hardware properties (**modified**)

Hardware Property	Subject Devices		Primary Predicate Device
	SOMATOM X.cite with syngo CT VA40	**SOMATOM X.ceed with syngo CT VA40**	**SOMATOM X.cite (K200524) syngo CT VA30**
Scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner
Generator max. power	90kW/105kW	105kW/120kW	105 kW
Detector technology	Stellar Infinity	Stellar Infinity	Stellar Infinity
Detector volume coverage	38.4 mm	38.4 mm	38.4 mm
Detector physical rows	64	64	64
Detector slice width	0.6 mm	0.6 mm	0.6 mm
Detector DAS channel No.	840	920	840
Detector image slices	128	128	128
Tube Technology	Vectron	Vectron	Vectron
Tube kV steps	(in 10kV steps) 70 kV to 150kV	(in 10kV steps) 70 kV to 150kV	(in 10kV steps) 70 kV to 150kV
Tube max. current	10 mA ~ 1100 mA; ≤ ±20% for 90 kW 10 mA ~ 1200 mA; ≤ ±20% for 105 kW	10 mA ~ 1200 mA; ≤ ±20% for 105 kW 10 mA ~ 1300 mA; ≤ ±20% for 120 kW	1200 mA
Tube tube focus	0.6 x 0.7 mm 0.8 x 1.1 mm	min. 0.6 x 0.7 mm (w/o comb) min. 0.4 x 0.5 mm (with comb)	0.6 x 0.7 mm 0.8 x 1.1 mm
Tube heat capacity	higher than 30 MHU	higher than 30 MHU	higher than 30 MHU
Gantry bore size	82 cm	82 cm	82 cm
Gantry FoV	50 cm	50 cm	50 cm
Gantry rotation time (sec)	0.3s/360°, 0.5s/360°, 1.0s/360°	0.25s/360°, 0.3s/360°, 0.5s/360°, 1.0s/360°	0.3, 0.5, 1.0
Gantry Tilt [degree]	'+/- 30° opt +/- 25° std	'+/- 30° opt +/- 25° std	+/- 25
Patient Table type	Vario RT: 1600mm, Vario 2: 2000mm Vitus: 2000mm	Vario RT: 1600mm, Vario 2.D: 2000mm, Vitus: 2000mm	Vario RT: 1600mm, Vario 2: 2000mm
Max. Scan length Topogram	VARIO RT: 1680 mm Vario 2: 2080 mm Vitus: 2080 mm	VARIO RT: 1680 mm Vario 2.D: 2080 mm Vitus: 2080 mm	VARIO RT: 1680 mm Vario 2: 2080 mm
Max. Scan length Image acquisition	VARIO RT: 1600 mm Vario 2: 2000 mm Vitus: 2000 mm	VARIO RT: 1600 mm Vario 2.D: 2000 mm Vitus: 2000 mm	VARIO RT:1600 mm Vario 2: 2000 mm
Spectral filtration Option*	Combined Split Filter / Tin Filter supported, plus extra Tin Filter	Combined Split Filter / Tin Filter supported, plus extra Tin Filter	Combined Split Filter / Tin Filter supported, plus extra Tin Filter
3D Camera	supported	supported	supported
High Power 70 (@70kV)	90kW Gen. @70kV = 1100mA 105kW Gen. @70kV = 1200mA	105kW Gen. @70kV = 1200mA 120kW Gen. @70kV = 1300mA	1100 mA 1200 mA
High Power 80 (@80kV)	90kW Gen. @80kV = 1100mA 105kW Gen. @80kV = 1200mA	105kW Gen. @80kV = 1200mA 120kW Gen. @80kV = 1300mA	1100 mA 1200 mA

Laser supported workflow	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position. myNeedle Laser visualize coordinates for intervention	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position. myNeedle Laser visualize coordinates for intervention	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position

The tabular summary of the comparable **software properties** between the subject devices with software version SOMARIS/10 syngo CT VA40 and the predicate devices are listed in **Table S5-06** below (modifications are in gray shaded sections).

Table S5-06: SOMATOM go. platform and SOMATOM X. platform comparable software properties

Software Property	***Subject Device***	***Predicate Device (K200524)***
	• **SOMATOM go.Now,** • **SOMATOM go.Up,** • **SOMATOM go.All,** • **SOMATOM go.Top,** • **SOMATOM go.Sim,** • **SOMATOM go.Open Pro,** • **SOMATOM X.cite,** • **SOMATOM X.ceed**	• **SOMATOM X.cite**
	syngo CT VA40	**syngo CT VA30**
Operating System	Windows based SOMARIS/10 syngo CT VA40 (with additional software options)	Windows based SOMARIS/10 syngo CT VA30A
Acquisition Workplace	syngo Acquisition Workplace (AWP)	syngo Acquisition Workplace (AWP)
	syngo Viewing, syngo Filming and syngo Archiving & Networking	syngo Viewing, syngo Filming and syngo Archiving & Networking
	Image Reconstruction	Image Reconstruction
	2nd Acquisition Workplace supported with myExam Satellite	No 2nd Acquisition Workplace supported
Stellar Detector	Stellar detector firmware supported	Stellar detector firmware supported
Teamplay	Support teamplay Protocols	Support teamplay Protocols
Protocols	• Protocols for Radiation Therapy Planning support patient marking • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols • Pediatric Protocols • Flex Dose Profile • TwinBeam DE • TwinSpiral DE • Flex 4D Spiral • Protocols that allow scanning with support of an 3rd party respiratory gating system (ANZAI, Varian RGSC)	• Protocols for Radiation Therapy Planning support patient marking • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols • Pediatric Protocols • Flex Dose Profile • TwinBeam DE • TwinSpiral DE • Flex 4D Spiral • Protocols that allow scanning with support of an 3rd party respiratory gating system (ANZAI, Varian RGSC)
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

Software Property	*Subject Device*	*Predicate Device (K200524)*
	• **SOMATOM go.Now,** • **SOMATOM go.Up,** • **SOMATOM go.All,** • **SOMATOM go.Top,** • **SOMATOM go.Sim,** • **SOMATOM go.Open Pro,** • **SOMATOM X.cite,** • **SOMATOM X.ceed**	• **SOMATOM X.cite**
	syngo CT VA40	**syngo CT VA30**
Post-Processing plug in functions	enabled via software interface **Recon&GO - Inline Results** (various methods of cleared software applications	enabled via software interface **Recon&GO - Inline Results** various methods of cleared software applications
Cybersecurity	IT Hardening	IT Hardening
HD FoV	HD FoV 4.0	HD FoV 4.0
Standard technologies	• FAST Features • CARE Features • GO technology	• FAST Features • CARE Features • GO technology
CT Guided Intervention	Guide&GO or myNeedle Guide (Note: Guide&GO is not supported by SOMATOM X.ceed)	Guide&GO
DirectDensity™	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 gating scan modes	Respiratory gated spiral and respiratory triggered sequence scan modes	Respiratory gated spiral and respiratory triggered sequence scan modes
Iterative Reconstruction Methods	iMAR, ADMIRE • (ADMIRE is enabled for go.All, go.Top, X.Cite and X.Ceed and not supported by SOMATOM go.Now, go.Up, go.Sim, go.Open Pro)	iMAR, ADMIRE
Precision Matrix	Precision Matrix resolution support image matrix sizes of 512 x 512 pixels, 768x768 pixels and 1024x1024 pixels (auto mode supported) (not for go.Now, go.Up and go.All)	Matrix resolution 512x512 pixels (auto mode not supported)
CaScoring	Offers images which can be used for calcium scoring, independent from tube voltage kV and beam filtration settings based on a dedicated single energy image reconstruction method.	Offers images which can be used for calcium scoring, independent from tube voltage kV and beam filtration settings based on a dedicated single energy image reconstruction method.

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation is completed. Test results show that the subject 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. platform during product development. The modifications described in this Premarket Notification were supported with this verification and validation testing.

Testing will be covered by 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)
- Test to support standards and regulations

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 were also performed as bench tests to support the new device or device modification on Non-Clinical Performance Testing as listed in table **S5-07** below.

Table S5-07: Non-Clinical Performance Testing

Feature/Non-Clinical Supportive Testing	Testing Performed
MyNeedle Laser	Bench Testing - The results of the accuracy test with a simulated clinical workflow and test setup show that defined accuracy level can be achieved.
MyNeedle Laser	Bench Testing - A comparison to the essential workflow steps was performed to demonstrate reduction in steps.
UHR imaging-Ultra High Resolution	Bench Testing - High Resolution across the whole FoV was evaluated and met the predetermined acceptance criteria.
Cardiac CT imaging - Motion artifact reduced ECG-gated imaging	Phantom Testing – Testing based on an andromorphic motion heart phantom (to mimic clinical performance) was performed to demonstrate support of the clinical claims.
Motion Artifact Reduced Non-Gated Imaging	Phantom Testing - Testing was completed based on an andromorphic motion heart and respiratory phantom to support the clinical claims

Feature/Non-Clinical Supportive Testing	Testing Performed
	based on technical phantom measurements, which are clinically realistic.
Cardiac BestPhase	Bench Testing - The automatic calculation of the cardiac reconstruction phase with minimized visible motion based on an ECG gated data set was completed. The testing demonstrated the feature met the requirements.
Equivalence of essential image quality parameters	Image Quality - The performed bench test provides substantial equivalence discussion about essential image quality parameters between SOMATOM X.ceed and SOMATOM X.cite – A number of tests were performed and evaluated (e.g. Image contrast values, image noise, contrast to noise ratio (CNR), noise power spectra)
Lung Cancer Screening	Bench Testing - Lung Cancer Screening Technological Parameters Comparison to support the new CT Scanner Model SOMATOM X.ceed was completed. This supports the indications for use accordingly for the new CT model.

A list of recognized and general consensus standards considered for the subject devices is provided as **Table S5-08** and **Table S5-09** below.

Table S5-08: 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
07/06/2020	12-325	NEMA	XR 25-2019	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
06/27/2016	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
12/23/2016	5-114	ANSI AAMI IEC	62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

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)] Note: Requirements according to IEC 60825-1:2014 (Ed.3.0) are implemented.
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)]
12/23/2019	12-328	IEC	61223-3-5 Edition 2.0 2019-09	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)]
12/23/2019	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 S5-09: 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	Declaration of conformance to FDA recognized consensus standards.

Standard Developing Organization	Standard Designation Number and Date	Title of Standard	How was Standard Used
		conformity – Part 1: General requirements	
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 S5-10** below.

Table S5-10: 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.

Cybersecurity

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**.**

Wireless and Wireless Coexistence

Siemens SOMATOM CT Scanners conform 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 tablets 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 with IEC60601-2-44.

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 the 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.

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 the software specifications have met the predetermined 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. and SOMATOM X. platforms should perform as intended in the specified use conditions.

The data included in this submission demonstrates that the SOMATOM go. platform and SOMATOM X. platform 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, that the data generated from the SOMATOM go. platform and SOMATOM X. platform (including the new SOMATOM X.ceed) testing supports a finding of substantial equivalence.