



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

November 21, 2019

Re: K192061

Trade/Device Name: SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.All,  
SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro and Scan&GO  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: Class II  
Product Code: JAK  
Dated: October 22, 2019  
Received: October 23, 2019

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](mailto: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

## Indications for Use

510(k) Number (if known)

K192061

Device Name

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

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.

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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  
PRASStaff@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."*

## Indications for Use

510(k) Number (if known)

K192061

Device Name

Scan & GO

Indications for Use (Describe)

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.

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 SCANNERS**  
**– SOFTWARE VERSION SOMARIS/10 syngo CT VA30**

Submitted by:  
Siemens Medical Solutions USA, Inc.  
810 Innovation Drive  
Knoxville, TN 37932  
Date Prepared: November 14, 2019

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**I. Submitter**

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

**Importer/Distributor**

Siemens Medical Solutions USA, Inc.  
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Malvern, PA 19355  
**Establishment Registration Number:** 2240869

**Location of Manufacturing Site (1)**

Siemens Healthcare GmbH  
Siemensstr. 1  
D-91301 Forchheim, Germany  
**Establishment Registration Number:** 3004977335

**Location of Manufacturing Site (2)**

SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD  
278 Zhou Zhu Rd  
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**Establishment Registration Number:** 3003202425

**Contact Person:**

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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

Trade Name: SOMATOM go.Now, SOMATOM go.Up,  
SOMATOM go.All, SOMATOM go.Top,  
SOMATOM go.Sim, SOMATOM go.Open Pro

Classification Name: Computed Tomography X-ray System  
Classification Panel: Radiology  
Regulation Number: 21 CFR §892.1750  
Device Class: Class II

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

### III. Predicate Device

#### Primary Predicate Device:

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

Note: K173632 was a bundle submission with various Siemens SOMATOM go.Platform CT Scanner Systems, including SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top 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.

#### Predicate Device:

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

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

## IV. Device Description

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

**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 Mobile Medical Application (optional mobile workflow component)

The subject device SOMATOM go.Platform with SOMARIS/10 syngo CT VA30 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 with Software SOMARIS/10 syngo CT VA30 produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens Healthcare and other vendors as an aid in diagnosis, treatment preparation and therapy planning support (including, but not limited to, Brachytherapy, Particle including Proton Therapy, External Beam Radiation Therapy, Surgery). The computer system delivered with the CT scanner is able to run optional post processing applications.

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

- Selection of patients
- Selection of pre-defined protocols
- Scan parameter display
- Patient table position display and gantry tilt parameter display
- Tools and instruction message area,
- Patient table position planning area
- Physiological data display
- Patient data display (e.g. date of birth, name)
- Display of acquired topogram and tomogram images
- Finalization of exam (close patient)
- Mobile Organizer,
- Patient Instruction Language (“API languages”)
- 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 for the SOMATOM go.Platform, syngo CT VA30 (SOMARIS/10 syngo CT VA30), is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The software platform SOMARIS/10 syngo CT VA30 is designed to provide a plugin interface to support the optional Scan&GO mobile workflow as well as integrate potential advanced post processing tasks, tools, or extendable functionalities. Software version syngo CT VA30 (SOMARIS/10 syngo CT VA30) is an update to software version syngo CT VA20A (SOMARIS/10 syngo CT VA20) which was cleared for the primary predicate devices in K173632, and supports the same plugin interfaces for the optional Scan&GO mobile workflow and integration of post-processing tasks as the predicate devices.

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

1) **New/Modified Hardware**

- Table S01: Overview of Hardware modifications

2) **Software version SOMARIS/10 syngo CT VA30**

- Table S02: Overview Software modifications of SOMATOM go.Platform with syngo CT VA30

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

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

**Table S01:** Overview of *Hardware Modifications* in comparison to the corresponding SOMATOM go.Platform predicate devices

SOMATOM go.Platform CT Scanner Systems with SOMARIS/10 syngo CT VA30							
#	hardware properties	Subject Devices SOMATOM go.Now	Subject Devices SOMATOM go.Up	Subject Devices SOMATOM go.All	Subject Devices SOMATOM go.Top	Subject Devices SOMATOM go.Sim	Subject Devices SOMATOM go.Open Pro
1	Patient Observation Camera	Unmodified	Unmodified	Unmodified	Unmodified	Modified	Modified
2	Moodlight	Unmodified	Unmodified	Unmodified	Unmodified	Modified	Modified
3	Various Tablet Configuration	Modified	Modified	Modified	Modified	Modified	Modified
4	High Power 70 / High Power 80	Unmodified	Unmodified	Unmodified	Unmodified	Enabled	Enabled
5	Adaptive Dose Shield	N/A	N/A	N/A	Enabled	N/A	Enabled
6	Tin Filter	Unmodified	Unmodified	Unmodified	Unmodified	Enabled	Enabled
7	Split Filter	N/A	N/A	N/A	Unmodified	N/A	Enabled
8	Integrated Patient Marking – Direct Laser	N/A	N/A	N/A	N/A	New	New
9	Other hardware modifications (e.g. new large bore size and FoV)	N/A	N/A	N/A	N/A	Modified	Modified

**Table S02:** Overview *Software modifications* of SOMATOM go.Platform with syngo CT VA30 in comparison to the corresponding SOMATOM go.Platform predicate devices

	SOMATOM CT System Scanner with SOMARIS/10 syngo CT VA30	Subject Devices	Subject Devices	Subject Devices	Subject Devices	Subject Devices	Subject Devices	Subject Devices
	Software properties	SOMATOM go.Now	SOMATOM go.Up	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.Sim	SOMATOM go.Open Pro	Scan&GO
1	MPPS	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled	N/A
2	Flex Dose Profile	Modified	Modified	Modified	Modified	Modified	Modified	N/A
3	Flex 4D Spiral	N/A	N/A	Modified	Modified	Modified	Modified	N/A
4	DirectDensity™	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled	N/A
5	Scan&GO - Mobile workflow	Modified	Modified	Modified	Modified	Modified	Modified	Modified
6	CT View&GO - Advanced tools	Modified	Modified	Modified	Modified	Modified	Modified	N/A



	<b>SOMATOM CT System Scanner with SOMARIS/10 syngo CT VA30</b>	<i>Subject Devices</i>	<i>Subject Devices</i>	<i>Subject Devices</i>	<i>Subject Devices</i>	<i>Subject Devices</i>	<i>Subject Devices</i>	<i>Subject Devices</i>
	<b>Software properties</b>	<b>SOMATOM go.Now</b>	<b>SOMATOM go.Up</b>	<b>SOMATOM go.All</b>	<b>SOMATOM go.Top</b>	<b>SOMATOM go.Sim</b>	<b>SOMATOM go.Open Pro</b>	<b>Scan&amp;GO</b>
7	Check&GO - Metal Detection	New	New	New	New	New	New	New
8	CARE Contrast III and Contrast media protocol	Modified	Modified	Modified	Modified	Modified	Modified	N/A
9	CARE kV	N/A	N/A	Modified	Modified	Modified	Modified	N/A
10	kV and Filter independent CaScore (Artificial120)	N/A	Enabled	Enabled	Enabled	Enabled	Enabled	N/A
11	Recon&GO – Advanced Reconstruction	Modified	Modified	Modified	Modified	Modified	Modified	N/A
12	Recon&GO – Post-Processing plug in functions	Modified	Modified	Modified	Modified	Modified	Modified	N/A
13	TwinBeam Dual Energy	N/A	N/A	N/A	Modified	N/A	Modified	N/A
14	TwinSpiral Dual Energy / TwinSpiral DE	Modified	Modified	Modified	Modified	Modified	Modified	N/A
15	FAST Planning, FAST Window	Modified	Modified	Modified	Modified	Modified	Modified	N/A
16	HD FoV 4.0	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled	N/A
17	Imaging – Exam workflow	New	New	New	New	New	New	New
18	Imaging - Cardio BestPhase	N/A	Enabled	Enabled	Enabled	Enabled	Enabled	N/A
19	Multistudy	Modified	Modified	Modified	Modified	Modified	Modified	N/A
20	Multiphase	N/A	N/A	Modified	Modified	Modified	Modified	N/A
21	Respiratory Motion Management	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled	N/A
22	Patient Marking - Direct Laser Steering	New	New	New	New	New	New	New
23	Direct i4D	N/A	N/A	N/A	N/A	N/A	New	N/A

A comparison of these modifications with respect to the predicate devices is provided in the “**Comparison of Technological Characteristics with the Predicate Device**” section below. Software version SOMARIS/10 syngo CT VA30 will be offered as an optional upgrade for the existing SOMATOM CT go.Platform Systems.

## 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 SOMATOM go. Platform scanners and optional Scan&GO mobile workflow provide the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software and hardware components of the SOMATOM go. Platform have been modified or improved in comparison to the predicate devices to support enhanced device functionality. The hardware components of the subject devices have been modified to support mobile workflow with multiple tablet configuration, a 3D Camera workflow for patient positioning, a larger bore size and an integrated laser system for patient marking to support treatment planning workflows.

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

The intended use and fundamental scientific technology for the SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim and SOMATOM go.Open Pro 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)
- 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 and the corresponding primary predicate devices of the SOMATOM go. Platform (K173632) and the predicate device SOMATOM Edge Plus (K190578):**

- Software version SOMARIS/10 syngo CT VA30
- Support of additional cybersecurity features
- Multiple tablet configuration for enhanced mobile workflow and control functionality
- Additional options for Inline and GO technologies
- CT protocol workflow enhanced functionality for advanced examination including parameter for scan protocol and contrast media.
- Interface to RTP Lasers (e.g. LAP, Siemens Direct Laser)

**The following technological differences exist between the subject device SOMATOM go.Sim and SOMATOM go.Open Pro and the predicate device SOMATOM go.Top (K173632) and the predicate device SOMATOM Edge Plus (K190578):**

- Software version SOMARIS/10 syngo CT VA30
- Support of additional cybersecurity features
- Multiple tablet configuration for enhanced mobile workflow and control functionality
- Additional options for Inline and GO technologies
- CT protocol workflow enhanced functionality for advanced examination including parameter for scan protocol and contrast media.
- Interface to RTP Lasers for Direct Laser Steering (e.g. in combination with 3rd party LAP laser system or Siemens integrated Direct Laser system)
- Optional integrated Laser System for patient marking
- CT gantry hardware supporting large bore size and 60 cm scan field-of-view

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

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

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

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

**Table S03: SOMATOM go.Platform comparable hardware properties**

Hardware Property	SOMATOM go.Platform - Device Comparison (Single Source Systems)						Primary Predicate Device
	Subject Device (software update)				Subject Device (new)		SOMATOM go.Top (K173632)
	SOMATOM go.Now	SOMATOM go.Up	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.Sim	SOMATOM go.Open Pro	
<b>Scanner</b>	whole body X-ray computed tomography scanner						
<b>Generator max. power</b>	32 kW	32 kW	75 kW	75 kW	75 kW	75 kW	75 kW
<b>Detector technology</b>	Stellar	Stellar	Stellar	Stellar	Stellar	Stellar	Stellar
<b>Detector volumen coverage</b>	11.2 mm	22.4 mm	22.4 mm	38.4 mm	19.2 mm	38.4 mm	38.4 mm
<b>Detector physical rows</b>	16	32	32	64	32	64	64
<b>Detector slice width</b>	0.7 mm	0.7 mm	0.7 mm	0.6 mm	0.6 mm	0.6 mm	0.6 mm
<b>Detector DAS channel No.</b>	768	768	768	840	920	920	840
<b>Detector image slices</b>	32	64	64	128	64	128	128
<b>Tube Technologie</b>	Chronon	Chronon	Athlon	Athlon	Athlon	Athlon	Athlon
<b>Tube kV steps</b>	(in 20kV steps) 80 kV to 130kV		(in 10kV steps) 70 kV to 140 kV				
<b>Tube max. current</b>	400 mA	400 mA	825 mA	825 mA	825 mA	825 mA	825 mA
<b>Tube tube focus</b>	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	1.0 x 1.2 0.8 x 0.8
<b>Tube heat capacity</b>	3.5 MHU	3.5 MHU	6 MHU	6 MHU	6 MHU	6 MHU	6 MHU
<b>Gantry bore size</b>	70 cm	70 cm	70 cm	70 cm	85 cm	85 cm	70 cm
<b>Gantry FoV</b>	50 cm	50 cm	50 cm	50 cm	60 cm	60 cm	50 cm
<b>Gantry rotation time (sec)</b>	0.8, 1.0, 1.5		0.33, 0.5, 1.0		0.35, 0.5, 1.0		0.33, 0.5, 1.0
<b>Gantry Tilt [degrees]</b>	N/A	+/-25	+/-25	+/-25	+/-25	+/-25	+/-25
<b>Patient Table type</b>	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 1 (1.600 m, Vario 2 (2.000m and Vario RT: 1.600 m with table extension
<b>Max. Scan length Topogram</b>	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
<b>Max. Scan length Image acquisition</b>	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
<b>Spectral filtration option</b>	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
<b>High Power 70</b>	N/A	N/A	825 mA (@ 70 kV)	825 mA (@ 70 kV)	825 mA (@ 70 kV)	825 mA (@ 70 kV)	825 mA (@ 70 kV)
<b>High Power 80</b>	N/A	N/A	825 mA (@ 80 kV)	825 mA (@ 80 kV)	825 mA (@ 80 kV)	825 mA (@ 80 kV)	825 mA (@ 80 kV)

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

**Table S04: SOMATOM go.Platform comparable software properties**

	<i>Subject Device</i>	<i>Primary Predicate Device</i>	<i>Predicate Device</i>
<i>Properties software</i>	<ul style="list-style-type: none"> <li>• SOMATOM go.Now,</li> <li>• SOMATOM go.Up,</li> <li>• SOMATOM go.All,</li> <li>• SOMATOM go.Top,</li> <li>• SOMATOM go.Sim,</li> <li>• SOMATOM go.Open Pro</li> </ul>	<ul style="list-style-type: none"> <li>• SOMATOM go.Now,</li> <li>• SOMATOM go.Up,</li> <li>• SOMATOM go.All,</li> <li>• SOMATOM go.Top</li> </ul>	<ul style="list-style-type: none"> <li>• SOMATOM Edge Plus</li> </ul>
	(syngo CT VA30)	(K173632)	(K190578)
Operating System	Windows based SOMARIS/10 syngo CT VA30	Windows based SOMARIS/10 syngo CT VA20A	Windows based SOMARIS/7 syngo CT VB20
Acquisition Workplace	syngo Acquisition Workplace (AWP)	syngo Acquisition Workplace (AWP)	syngo Acquisition Workplace (AWP)
	syngo Viewing, syngo Filming and syngo Archiving & Networking	syngo Viewing, syngo Filming and syngo Archiving & Networking	syngo Viewing, syngo Filming and syngo Archiving & Networking
	Image Reconstruction	Image Reconstruction	Image Reconstruction
Stellar Detector	Stellar detector firmware supported	Stellar detector firmware supported	Stellar detector firmware supported
Teampay	Support teampay Protocols	Support teampay Protocols	Support teampay Protocols
Protocols	Support of: <ul style="list-style-type: none"> <li>• Protocols for Radiation Therapy Planning support patient marking</li> <li>• Protocols that allow scanning with support of an external respiratory gating system (ANZAI, Varian RGSC)</li> <li>• Protocol supporting contrast bolus-triggered data acquisition</li> <li>• Contrast media protocols</li> <li>• Pediatric Protocols</li> <li>• Flex Dose Profile</li> <li>• TwinBeam DE</li> <li>• TwinSpiral DE</li> <li>• Flex 4D Spiral</li> </ul>	Support of: <ul style="list-style-type: none"> <li>• Protocols for Radiation Therapy Planning</li> <li>• Protocol supporting contrast bolus-triggered data acquisition</li> <li>• Pediatric Protocols</li> </ul>	Support of : <ul style="list-style-type: none"> <li>• Protocols for Radiation Therapy Planning</li> <li>• Protocols for Radiation Therapy Planning</li> <li>• Protocols that allow triggering of breath hold scanning from external device.</li> <li>• Protocol supporting contrast bolus-triggered data acquisition</li> <li>• Pediatric Protocols</li> <li>• Adaptive Dose Area</li> <li>• DualSource DE</li> <li>• Adaptive 4D Spiral</li> </ul>
<b>post-processing methods</b> (syngo CT VA30 enable a subset of methods on the scanner software installation – only applicable for previously cleared syngo.CT applications)	enabled via software interface Recon&GO - Inline Results <b>varies methods contained in the available applications</b> syngo.CT Coronary Analysis syngo.CT Vascular Analysis syngo.CT Dual Energy syngo.CT Bone Reading syngo.via RT Image Suite <b>Note 1:</b> Detailed information about the subset of enabled syngo.CT functionalities is listed below.	enabled via software interface Recon&GO - Inline Results <b>varies methods contained in the available applications</b> syngo.CT Vascular Analysis, syngo.CT Bone Reading, syngo.CT MM Oncology, syngo.CT Dual Energy syngo.via (incl. MM Reading, ALPHA technology) syngo.CT Clinical Extensions syngo.CT LungCAD syngo.via RT Image Suite	enabled via stand-alone workplace software installation <b>varies methods contained in the available applications</b> The user will operate the SOM/7-based scanner workplace and in addition have the possibility to use post-processing applications provided by a syngo.via-based system on the acquisition workplace.
Cybersecurity	IT Hardening	IT Hardening	IT Hardening
HD FoV	HD FoV 4.0	HD FoV 3.0	HD FoV 4.0
Standard technologies	<ul style="list-style-type: none"> <li>• FAST Features</li> <li>• CARE Features</li> <li>• GO technology</li> </ul>	<ul style="list-style-type: none"> <li>• FAST Features</li> <li>• CARE Features</li> <li>• GO technology</li> </ul>	<ul style="list-style-type: none"> <li>• FAST Features</li> <li>• CARE Features</li> </ul>
DirectDensity™	DirectDensity™ (including relative electron density and relative mass density)	N/A	DirectDensity™ (including relative electron density and relative mass density)

	<i>Subject Device</i>	<i>Primary Predicate Device</i>	<i>Predicate Device</i>
<i>Properties software</i>	<ul style="list-style-type: none"> <li>• SOMATOM go.Now,</li> <li>• SOMATOM go.Up,</li> <li>• SOMATOM go.All,</li> <li>• SOMATOM go.Top,</li> <li>• SOMATOM go.Sim,</li> <li>• SOMATOM go.Open Pro</li> </ul> (syngo CT VA30)	<ul style="list-style-type: none"> <li>• SOMATOM go.Now,</li> <li>• SOMATOM go.Up,</li> <li>• SOMATOM go.All,</li> <li>• SOMATOM go.Top</li> </ul> (K173632)	<ul style="list-style-type: none"> <li>• SOMATOM Edge Plus</li> </ul> (K190578)
breath-hold technique	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations.	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations.	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations and DirectBreathhold™ (automated trigger supported)
Respiratory gating scan modes	Respiratory gated spiral and respiratory triggered sequence scan modes	Respiratory gated spiral scan mode	Respiratory gated spiral scan mode, automatically triggered prospective spiral scan mode
Iterative Reconstruction Methods	<ul style="list-style-type: none"> <li>• SAFIRE</li> <li>• iMAR</li> </ul>	<ul style="list-style-type: none"> <li>• SAFIRE</li> <li>• iMAR</li> </ul>	<ul style="list-style-type: none"> <li>• ADMIRE</li> <li>• SAFIRE</li> <li>• iMAR</li> </ul>

**Note 1: Detail information to support Recon&GO**

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

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

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

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

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

Recon&GO – Advanced Reconstruction	510(k) information of the medical device software application that support <u>same reconstruction tools</u>
urine testing. Only a well-trained radiologist can make the final diagnosis under consideration of all available information. The accuracy of identification is decreased in obese patients.	

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

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

<b>Enabled Recon&amp;GO – Post-Processing plug in functions</b>	510(k) information of the medical device software application that support <u>same</u> established post-processing methods
Heart Isolation, Coronary Tree, Vessel Ranges (LAD, RCA, CX), Cardiac Ranges	Reference Device K173637 – syngo.CT Coronary Analysis
Vascular ranges (Aorta, Carotis L Int., Carotic R Int., Runoff L, Runoff R) Inline Table removal, Inline Bone removal	Reference Device K173637 – syngo.CT Vascular Analysis
Lung CAD – Supported by SOMATOM go.Now, go.Up, go.All and go.Top	Reference Device K143196 – syngo.CT LungCAD
Anatomical ranges (Parallel/Radial) – Supported by SOMATOM go.Now, go.Up, go.All and go.Top	Reference Device K150843 - syngo.via software version VB10 support (Organ Ranges)
Radial Rib Ranges, Parallel Rib Ranges and Spine Range	Reference Device K123584 - syngo.CT Bone Reading
3D and 4D image visualization, manipulation and manual contouring tools for preparation and response assessment of radiotherapy treatment.	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 during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

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

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

#### System Test (ST):

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

#### System Integration Test (SIT):

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

**Subsystem Integration Test (SSIT):**

- Subsystem Integration Test
- DICOM tests

Tests are conducted for all software components developed in product development and for the complete product itself. Several activities are 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 S07 below.

**Table S07:** Non-Clinical Performance Testing

#	Feature/Non-Clinical Supportive Testing	Document Title	Testing Performed
01	kV and Filter independent CaScore	Evaluation of DirectDensity and Artificial120 kernels on Somaris/10 VA30	The test results show that performance of special kernel variants Artificial120 and eDDensity and mDDensity is similar or improved within the limits of accuracy of the test compared to the respective initial release versions. In conclusion, the features DirectDensity and Calcium Scoring at any kV have been enabled for the release SOMARIS/10 VA30.
02	Recon&GO - Spectral Recon	Detailed Description and Bench Test for the Feature "Spectral Recon"	Deviations between the already cleared image processing algorithms in Inline DE and the new technical realization "Spectral Recon" are extremely small and are not expected to have any impact on the diagnostic performance. Residual deviations are a consequence of rounding differences and slight differences in implementation.
03	TwinSpiral Dual Energy / TwinSpiral DE	Detailed Description and Bench Test for the Feature "TwinSpiral"	Based on these results it can be stated that the TwinSpiral Dual Energy CT scan mode provides CT-images of diagnostic quality, which are similar to conventional 120kV images in terms of CT-values and image noise at same radiation dose. The mixed images show a slight reduction in the iodine CT-value, but at the same time image noise at same dose is also lower. So in combination the iodine CNR at same radiation dose is comparable between Mixed images and 120kV images.
04	Flex 4D Spiral - Neuro/Body	Flex4D Spiral: Technical principals and demonstration of freely selectable scan ranges (Somaris/10 VA30)	Scan ranges with the new Flex4D Spiral feature can be freely selected within the limits mandated by the scan mode and protocol. The scanned volume was found to be in agreement with the planned scan range for a variety of different tested scan modes, scan lengths and scanners. Radiochromic film placed in the isocenter for a variety of scan ranges showed that the irradiated range markers displayed by the scanner acquisition software during the planning of the respective F4DS scans were in good agreement with the exposed area on the film.
05	DirectDensity	Evaluation of DirectDensity and Artificial120 kernels on Somaris/10 VA30	Evaluation of phantom images to demonstrate the subject device features ability to provide images that can be shown as relative mass density or relative electron density. The conducted test performed demonstrated the subject device's ability to show relative mass or relative electron density images.
06	HD FoV	HDFoV 4.0: Technical principals and phantom	Phantom testing conducted to assess the subject device ability to provide visualization of anatomies outside the



#	Feature/Non-Clinical Supportive Testing	Document Title	Testing Performed
		measurements evaluating HU accuracy and skin-line accuracy in the extended field of view (FoV) region (Som/10 VA30)	standard field of view and that the image quality standards for radiotherapy applications are met.
07	Contrast media protocol	Siemens Healthineers factory contrast protocols and comparison to approved drug labeling	All Factory Contrast Protocols are within the limits as prescribed by the approved labeling of Ultravist®". (no protocol for coronary CTA)
08	InjectorCoupling	Siemens Healthineers Injection Parameter Exchange Validation	Correctness of the contrast injection parameters transferred between the CT device and the supported injection devices has been verified.
09	Direct i4D	Assessment of Direct i4D	The test results show that with Direct i4D it is possible to acquire data for a full breathing cycle at every position of the patient even if the respiratory rate changes during the data acquisition. Compared to the conventional 4DCT scan mode interpolation artifacts (which occur because not for every position a complete breathing cycle could be acquired) can successfully be avoided with Direct i4D.
10	Check&GO	Detailed Description and Bench Test for the Feature "Check&GO"	500 CT-series from 100 patients were used for the testing of the algorithm. The datasets were manually annotated with a detailed GT contrast-state (None, Low, InhomogeneousLow, Standard, InhomogeneousHigh, High). Check&GO feature can be proven helpful in aiding the user to reduce instances where the image quality may be compromised.
11	Siemens Direct Laser (RTP Laser)	Unit Test Report	RTP-Laser Electronics – Test specification (Unit) Version 00 and Report - General Requirements - Mechanics, Connectors - Function requirements  Attachment 12 to Report CN19-003-AU01-S01-TR31 - Test for the new RTP Laser Unit 10830876 - Integral Light Markers For Patient Marking (IEC 60601-2-44)

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the 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 S08** and **Table S09** below.

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)	<u>Digital Imaging And Communications In Medicine (DICOM) Set</u>
03/14/2011	12-225	NEMA	XR-25	<u>Computed Tomography Dose Check</u>
01/27/2015	12-287	NEMA	XR-28 2013	<u>Supplemental Requirements For User Information And System Function Related To Dose In CT</u>

**Table S08: Recognized Consensus Standards**

<b>Date of Recognition</b>	<b>Recognition Number</b>	<b>Standard Developing Organization</b>	<b>Standard Designation Number and Date</b>	<b>Title of Standard</b>
6/27/2016	5-40	ANSI AAMI ISO	14971:2007/(R)2010 (Corrected 4 October 2007)	<u>Medical Devices - Applications Of Risk Management To Medical Devices</u>
		ISO	14971 Second Edition 2007-03-01	<u>Medical Devices - Applications Of Risk Management To Medical Devices</u>
01/14/2019	13-79	IEC	62304 Edition 1.1 2015- 06 CONSOLIDATED VERSION	<u>Medical Device Software - Software Life Cycle Processes</u>
07/09/2014	19-4	ANSI AAMI	ES60601-1:2005/(R)2012 And A1:2012,	<u>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)</u>
09/17/2018	19-8	ANSI AAMI IEC	60601-1-2:2014	<u>Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests</u>
7212/23/2016	5-114	ANSI AAMI IEC	62366-1:2015	<u>Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices</u>
07/09/2014	12-273	IEC	60825-1 Edition 2.0 2007-03	<u>Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]</u>
06/27/2016	12-302	IEC	60601-2-44 Edition 3.2: 2016	<u>Medical Electrical Equipment - Part 2-44: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Computed Tomography</u>
01/14/2014	12-269	IEC	60601-1-3 Edition 2.1 2013-04	<u>Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment</u>
06/27/2016	5-89	IEC	60601-1-6 Edition 3.1 2013-10	<u>Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability</u>
03/14/2011	12-226	IEC	61223-2-6 Second Edition 2006-11	<u>Evaluation And Routine Testing In Medical Imaging Departments - Part 2-6: Constancy Tests - Imaging Performance Of Computed Tomography X-Ray Equipment</u>
01/30/2014	12-270	IEC	61223-3-5 First Edition 2004-08	<u>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)]</u>
06/07/2018	12-309	IEC	60601-2-28 Edition 3.0 2017-06	<u>Medical Electrical Equipment - Part 2-28: Particular Requirements For The Basic Safety And Essential</u>

Table S08: Recognized Consensus Standards				
Date of Recognition	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				<u>Performance Of X-Ray Tube Assemblies For Medical Diagnosis</u>
06/27/2016	12-299	IEC	62563-1 Edition 1.1	<u>Medical Electrical Equipment - Medical Image Display Systems - Part 1: Evaluation Methods</u>

Table S09: General Use Consensus Standards			
Standard Developing Organization	Standard Designation Number and Date	Title of Standard	How was Standard Used
IEC	60601-1:2005+A1:2012	Medical electrical equipment - part 1: general requirements for basic safety and essential performance	Covered by ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 as part of EMC testing.
IEC/ISO	17050-1	Conformity Assessment – Supplier’s declaration of conformity – Part 1: General requirements	Declaration of conformance to FDA recognized consensus standards.
IEC/ISO	17050-2	Conformity assessment – Supplier’s declaration of 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 S10** below.

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

Table S10 FDA Guidance Document and Effective Date	
	Document Issued on September 6, 2017
13.	Guidance for Industry and Food Drug Administration Staff: <b>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</b> 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 visualization 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 should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM go. 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, Siemens believes that the data generated from the SOMATOM go. Platform testing supports a finding of substantial equivalence.