July 3, 2025

Siemens Medical Solutions USA, Inc.
℅ Kenny M Bello
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE, TN 37932

Re: K250822
   Trade/Device Name: SOMATOM go.Now; SOMATOM go.Up; SOMATOM go.All; SOMATOM
                  go.Top; SOMATOM go.Sim; SOMATOM go.Open Pro; SOMATOM Pro.Pulse
   Regulation Number: 21 CFR 892.1750
   Regulation Name: Computed Tomography X-Ray System
   Regulatory Class: Class II
   Product Code: JAK
   Dated: May 16, 2025
   Received: June 16, 2025

Dear Kenny M Bello:

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 (the 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
available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
 Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K250822

Device Name
SOMATOM go.Now; SOMATOM go.Up; SOMATOM go.All; SOMATOM go.Top; SOMATOM go.Sim; SOMATOM go.Open Pro; SOMATOM Pro.Pulse

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 staff as an aid in diagnosis, treatment, and radiation therapy planning as well as for diagnostic and therapeutic interventions.

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.

SIEMENS
Healthineers

510(k) Summary

SOMATOM go. Platform and SOMATOM Pro.Pulse
with software version SOMARIS/10 *syngo* CT VB20

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. Contact Details

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

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

Location of Manufacturing Site (1)
Siemens Healthineers AG
Siemensstr. 1 -OR- Rittigfeld 1
D-91301 Forchheim, Germany
Establishment Registration Number: 3004977335

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

Note: Descriptions in this submission use the short company name Siemens. It covers both manufacturing locations and names as listed above. Brand name on all products is Siemens Healthineers.

SIEMENS
Healthineers

Submitter Contact Person:

Kenny M Bello

Regulatory Affairs Professional

Siemens Medical Solutions USA, Inc.

Molecular Imaging

810 Innovation Drive

Knoxville, TN 37932

Phone: (205) 856-6099

monsuru.bello@siemens-healthineers.com

II. Device Name and Classification

Table 1: Subject Device Names

Product Name	Trade Name
SOMATOM go.Now	SOMATOM go.Now
SOMATOM go.Up	SOMATOM go.Up
SOMATOM go.All	SOMATOM go.All
SOMATOM go.Top	SOMATOM go.Top
SOMATOM go.Sim	SOMATOM go.Sim
SOMATOM go.Open Pro	SOMATOM go.Open Pro
SOMATOM Pro.Pulse	SOMATOM Pro.Pulse

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 Name: SOMATOM go. Platform CT Scanner Systems with SOMARIS/10 *syngo* CT VB10 software
510(k) Number: K233650
Clearance Date: March 26, 2024
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.

Secondary predicate device:

Trade Name:	SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10 software
510(k) Number:	K232206
Clearance Date:	December 6, 2024
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:

K233650 was a bundle submission with various Siemens CT Scanner Systems, including the CT scanner systems 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.

IV. Device Description

Siemens intends to market a new software version, SOMARIS/10 *syngo* CT VB20 for the following SOMATOM Computed Tomography (CT) Scanner Systems:

   a) **Single Source CT Scanner systems (SOMATOM go. Platform):**
   - SOMATOM go.Now
   - SOMATOM go.Up
   - SOMATOM go.All
   - SOMATOM go.Top
   - SOMATOM go.Sim
   - SOMATOM go.Open Pro

In this submission, the above listed CT scanner systems are jointly referred to as subject devices by "SOMATOM go. Platform" CT scanner systems.

   b) **Dual Source CT Scanner system:**
   - SOMATOM Pro.Pulse

The above listed subject devices with SOMARIS/10 *syngo* CT VB20 are Computed Tomography X-ray Systems which feature one (Single Source) or two (Dual Source) continuously rotating tube-detector system and function according to the fan beam principle. The SOMATOM go. Platform and the SOMATOM Pro.Pulse with software SOMARIS/10 *syngo* CT VB20 produce CT images in DICOM format, which can be used by trained staff for software applications, e.g. 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.

Only trained and qualified users, certified in accordance with country-specific regulations, are authorized to operate the system. For example, physicians, radiologists, or technologists. The user must have the necessary U.S. qualifications in order to diagnose or treat the patient with the use of the images delivered by the system.

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

New software version syngo CT VB20 (SOMARIS/10 syngo CT VB20) is a modified software version based on syngo CT VB10 (SOMARIS/10 syngo CT VB10) which was cleared for the predicate devices in K233650 (SOMATOM go. Platform) and in K232206 (SOMATOM Pro.Pulse).

Software version SOMARIS/10 syngo CT VB20 will be offered ex-factory and as an optional upgrade for the applicable existing SOMATOM go. Platform and SOMATOM Pro.Pulse CT Scanner Systems.

The bundle approach is feasible for this submission since the subject devices have similar technological characteristics, software operating platform, and supported software characteristics. The supporting data are similar, primarily one review division/group will be involved, and the indications for use is the same between the devices. All subject devices will support previously cleared software and hardware features in addition to the applicable modifications as described within this submission. The intended use remains unchanged compared to 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 staff as an aid in diagnosis, treatment, and radiation therapy planning as well as for diagnostic and therapeutic interventions.

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. Indications for Use Comparison

Subject Device 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 staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.

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

SIEMENS ∵:
Healthineers

* 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.

Primary Predicate Device 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 staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.

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.

Secondary Predicate Device 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 trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.

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.

Comparison:

The subject device Indications for Use is the exact same as the primary (K233650) and the secondary (K232206) predicate's Indications for Use. As such, the Indications for Use remains unchanged from the predicate devices and is substantially equivalent to the predicate devices.

VII. Comparison of Technological Characteristics with the Predicate Device

Supported by the subject device, SOMARIS/10 *syngo* CT VB20 software version is a further development of the SOMARIS/10 *syngo* CT VB10 software version which is cleared in K233650 and K232206.

The SOMATOM go. Platform and SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB20 software version provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software features of the SOMATOM go. Platform and SOMATOM Pro.Pulse have been modified or improved in comparison to the predicate devices to support enhanced device functionality compared to the predicate devices.

The new *syngo* CT VB20 software reuses all unmodified software features of the legacy software *syngo* CT VB10 cleared in K233650 and K232206. Additionally, no features present in the predicate device are descoped.

Software version SOMARIS/10 *syngo* CT VB20 is designed to reuse hardware independent extended functionalities and GO technologies provided by Siemens cleared software applications.

The intended use and fundamental scientific technology for the SOMATOM go. Platform and SOMATOM Pro.Pulse remain unchanged from the predicate devices.

At a high level, the subject and predicate devices are based on the same subset of 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 principles
- Workplaces – Support of workplaces that include reconstruction and image evaluation software
- Patient table
- Patient table foot switch for movement
- Stellar Detector technology
- Tin filtration technology
- Athlon/Vectron X-ray Tube
- Power Generator
- Scan&GO
- Mobile workflow (Tablet)
- Optional injector arm
- Optional support of CT guided intervention workflow (myNeedle Companion – myNeedle Guide)
- Optional support of FAST 3D Camera for patient positioning workflow
- Scanner display and control functionality
- Remote Scan Control
- Interfaces for Respiratory Gating Devices
- Standard CARE technologies
- Standard FAST technologies
- Standard GO technologies
- Precision matrix (large image matrices)
- HD FoV
- DirectDensity
- Stack artefact reduced reconstruction

The terms in the following Table 2 are used to indicate various technological characteristics in comparison to the primary and secondary predicate devices information:

Table 2: Overview of term definition.

Term	Definition
new	The feature is newly supported for Siemens CT Scanners and newly introduced within the subject device submission

Term	Definition
modified	This feature is modified from the predicate devices
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 VB20 and is substantially equivalent compared to the cleared version of the predicate devices.
unmodified	The feature remains unchanged from the predicate device.
n.a.	The feature is not supported for the subject/predicate device

The subject devices SOMATOM go. Platform and SOMATOM Pro.Pulse CT scanner systems with SOMARIS/10 *syngo* CT VB20 will support hardware and software modifications/further developments in comparison to the predicate devices as listed in Table 3. The column "HW/ SW change" in the table contains reference to a hardware (HW) or/and software (SW) change. The columns under "Predicate devices" of the Table 3 indicate the clearance of the technological properties in the corresponding predicate device.

Table 3: Summary of modifications (hardware and software) of the subject devices SOMATOM go. Platform and SOMATOM Pro.Pulse with software version SOMARIS/10 syngo CT VB20 compared to the predicate devices.

	Technological property	HW/SW change	Subject devices		Predicate devices	
			Single Source	Dual Source	Single Source	Dual Source
			SOMATOM go. Platform with *syngo* CT VB20	**SOMATOM Pro.Pulse** with *syngo* CT VB20	**SOMATOM go. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM Pro.Pulse** with *syngo* CT VB10 (K232206)
1.	CARE Moodlight	HW/SW	**enabled[1]** (same as in K233650)	**unmodified**	cleared	cleared
2.	Interfaces for respiratory gating	HW	**modified[2]** (same as in K233650, with exception of Open Online Interface which are introduced with *syngo* CT VB20)	**n.a.**	cleared	n.a.
3.	Eco Power Mode	HW/SW	**new[3]**	**new**	n.a.	n.a.

[1] In software version *syngo* CT VB20, the functionality CARE Moodlight is enabled for the subject devices SOMATOM go.Sim and SOMATOM go.Open Pro. For the subject devices SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, and SOMATOM go.Top, the functionality CARE Moodlight was cleared in K233650 and it remains unchanged in software version *syngo* CT VB20.

[2] SOMATOM go.Now does not support respiratory gating interfaces.

[3] SOMATOM go.Now and SOMATOM go.Up do not support Eco Power Mode.

	Technological property	HW/SW change	Subject devices		Predicate devices	
			Single Source	Dual Source	Single Source	Dual Source
			SOMATOM go. Platform with *syngo* CT VB20	**SOMATOM Pro.Pulse** with *syngo* CT VB20	**SOMATOM go. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM Pro.Pulse** with *syngo* CT VB10 (K232206)
4.	FAST 3D Camera/ FAST Integrated Workflow	SW	**modified** (same as in K233650, with exception of retrained FAST 3D Camera algorithms, collision indication, and Centerline/Grid Overlay which are introduced with *syngo* CT VB20)	**modified** (same as in K232206, with exception of retrained FAST 3D Camera algorithms, collision indication, and Centerline/Grid Overlay which are introduced with *syngo* CT VB20)	cleared	cleared
5.	Oncology Exchange	SW	**new**	**new**	n.a.	n.a.
6.	DirectSetup Notes	SW	**enabled**[4] (same as in K233650)	**enabled**[4] (same as in K233650)	cleared	n.a.
7.	FAST Planning	SW	**modified** (same as in K233650, with exception of the detection	**modified** (same as in K232206, with exception of the detection	cleared	cleared

---

[4] In software version *syngo* CT VB20, the functionality DirectSetup Notes is enabled for the subject devices SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, and SOMATOM Pro.Pulse. For the subject devices SOMATOM go.Sim and SOMATOM go.Open Pro, the functionality DirectSetup Notes was cleared in K233650 and it remains unchanged in software version *syngo* CT VB20.

	Technological property	HW/SW change	Subject devices		Predicate devices	
			Single Source	Dual Source	Single Source	Dual Source
			SOMATOM go. Platform with *syngo* CT VB20	**SOMATOM Pro.Pulse** with *syngo* CT VB20	**SOMATOM go. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM Pro.Pulse** with *syngo* CT VB10 (K232206)
			of additional body regions which are introduced with *syngo* CT VB20)	of additional body regions which are introduced with *syngo* CT VB20)		
8.	myExam Companion – myExam Compass/myExam Cockpit	SW	**modified** (same as in K233650, with exception of the clinical decision trees now also available for child protocols)	**modified** (same as in K233650, with exception of the clinical decision trees now also available for child protocols)	cleared	cleared
9.	HD FoV 5.0	SW	**new**[5]	**n.a.**	n.a.	n.a.
10.	CT guided intervention – myAblation Guide interface	SW	**new**	**new**	n.a.	n.a.
11.	Flex 4D Spiral	SW	**modified**[6]	**modified**	cleared[6]	cleared

---

[5] In software version *syngo* CT VB20, the functionality HD FoV 5.0 is introduced only for the subject devices SOMATOM go.Sim and SOMATOM go.Open Pro.

[6] The CT scanner CT systems SOMATOM go.Now and SOMATOM go.Up do not support Flex 4D Spiral.

	Technological property	HW/SW change	Subject devices		Predicate devices	
			Single Source	Dual Source	Single Source	Dual Source
			SOMATOM go. Platform with *syngo* CT VB20	**SOMATOM Pro.Pulse** with *syngo* CT VB20	**SOMATOM go. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM Pro.Pulse** with *syngo* CT VB10 (K232206)
			(same as in K233650, with exception of the modifications regarding dynamic tube current modulation which is introduced with *syngo* CT VB20)	(same as in K233650, with exception of the modifications regarding dynamic tube current modulation which is introduced with *syngo* CT VB20)		
12.	ZeeFree RT	SW	**new**[7]	n.a.	n.a.	n.a.
13.	DirectDensity	SW	**modified** (same as in K233650, with exception of the calculation of stopping-power ratio (Kernel St) which is introduced with *syngo* CT VB20)	**modified** (same as in K233650, with exception of the calculation of stopping-power ratio (Kernel St) which is introduced with *syngo* CT VB20)	cleared	cleared
14.	DirectLaser	HW/SW	**modified**[8]	**n.a.**	cleared[8]	n.a.

[7] In software version *syngo* CT VB20, the functionality ZeeFree RT is introduced only for the subject device SOMATOM go.Open Pro.

[8] DirectLaser is available only for SOMATOM go.Sim and SOMATOM go.Open Pro.

	Technological property	HW/SW change	Subject devices		Predicate devices	
			Single Source	Dual Source	Single Source	Dual Source
			SOMATOM go. Platform with *syngo* CT VB20	**SOMATOM Pro.Pulse** with *syngo* CT VB20	**SOMATOM go. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM Pro.Pulse** with *syngo* CT VB10 (K232206)
			(same as in K233650, with exception of the Patient Marking workflow improvement introduced with *syngo* CT VB20)			
15.	myExam Contrast	SW	**new**	**new**	n.a.	n.a.

A tabular summary of the comparable hardware and software properties between the subject devices SOMATOM go. Platform and SOMATOM Pro.Pulse with software version *syngo* CT VB20 and the predicate devices are listed in Table 4 through Table 8 below (modifications are in gray shaded sections).

Table 4 provides comparison of the hardware properties between the single source subject devices SOMATOM go.Now and SOMATOM go.Up with software version *syngo* CT VB20 and the predicate devices SOMATOM go.Now and SOMATOM go.Up with software version *syngo* CT VB10 (K233650).

Table 5 provides comparison of the hardware properties between the single source subject devices SOMATOM go.All and SOMATOM go.Top with software version *syngo* CT VB20 and the predicate devices SOMATOM go.All and SOMATOM go.Top with software version *syngo* CT VB10 (K233650).

Table 6 provides comparison of the hardware properties between the single source subject devices SOMATOM go.Sim and SOMATOM go.Open Pro with software version *syngo* CT VB20 and the predicate devices SOMATOM go.Sim and SOMATOM go.Open.Pro with software version *syngo* CT VB10 (K233650).

Table 7 provides comparison of the hardware properties between the dual source subject device SOMATOM Pro.Pulse with software version *syngo* CT VB20 and the predicate devices SOMATOM Pro.Pulse (K233650) and SOMATOM go.Top with software version *syngo* CT VB10 (233650).

Table 8 compares the software technological characteristics of the subject devices and the predicate devices.

Table 4: Comparison of technical hardware characteristics between the subject devices SOMATOM go.Now and SOMATOM go.Up with software version syngo CT VB20 and the primary predicate devices SOMATOM go.Now and SOMATOM go.Up with software version syngo CT VB10 (K233650).

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Now	SOMATOM go.Up	SOMATOM go.Now	SOMATOM go.Up	
scanner	Whole body Computed Tomography (CT) Scanner System		Whole body Computed Tomography (CT) Scanner System		Same as the primary predicate devices
System Configuration	Single Source		Single Source		Same as the primary predicate devices

SIEMENS ·.·.·
Healthineers ·:·

Hardware property	Subject device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Now	**SOMATOM go.Up**	**SOMATOM go.Now**	**SOMATOM go.Up**	
Environment of Use	Professional Healthcare Facility		Professional Healthcare Facility		Same as the primary predicate devices
Generator Max. power (kW)	32		32		Same as the primary predicate devices
Detector technology	Stellar based on UFC (Ultra Fast Ceramic)		Stellar based on UFC (Ultra Fast Ceramic)		Same as the primary predicate devices
Detector volume coverage (mm)	11.2	22.4	11.2	22.4	Same as the primary predicate devices
Detector physical rows	16	32	16	32	Same as the primary predicate devices
Detector Slice width (mm)	0.7		0.7		Same as the primary predicate devices
Detector DAS channel no.	768		768		Same as the primary predicate devices
Detector Image slices	32	64	32	64	Same as the primary predicate devices
Tube technology	Chronon		Chronon		Same as the primary predicate devices

SIEMENS ∴∴∴
Healthineers ∴∴∴

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Now	SOMATOM go.Up	SOMATOM go.Now	SOMATOM go.Up	
Tube kV steps	80, 110, 130		80, 110, 130		Same as the primary predicate devices
Tube Max. current (mA)	400		400		Same as the primary predicate devices
Tube focus	• 0.8 x 0.4 / 8° • 0.8 x 0.7 / 8°		• 0.8 x 0.4 / 8° • 0.8 x 0.7 / 8°		Same as the primary predicate devices
Tube Heat storage capacity (MHU)	3.5		3.5		Same as the primary predicate devices
Tube Cooling rate (kHU/ min)	915		915		Same as the primary predicate devices
Gantry Bore size	70		70		Same as the primary predicate devices
Gantry Scan FoV (cm)	50		50		Same as the primary predicate devices
Gantry Extended FoV (cm)	70		70		Same as the primary predicate devices
Gantry Rot. time (sec)	0.5, 0.8, 1.0, 1.5		0.5, 0.8, 1.0, 1.5		Same as the primary predicate devices

SIEMENS **Healthineers**

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Now	**SOMATOM go.Up**	**SOMATOM go.Now**	**SOMATOM go.Up**	
Gantry Tilt (degree)	n.a.	+/- 30° -30° to +28° with optional 307 kg patient table	n.a.	+/- 30° -30° to +28° with optional 307 kg patient table	Same as the primary predicate devices
Patient table Type	Vector (1250 mm), Vario 1 (1600 mm), Vario RT (1600 mm) with table extension	Vario 1 (1600 mm), Vario 2 (2000 mm), Vario RT (1600 mm) with table extension	Vector (1250 mm), Vario 1 (1600 mm), Vario RT (1600 mm) with table extension	Vario 1 (1600 mm), Vario 2 (2000 mm), Vario RT (1600 mm) with table extension	Same as the primary predicate devices
Patient table Max. weight capacity (kg)	Vector: 160 Vario 1: 227 Vario RT: 227	Vario 1: 227 Vario 2: 307 Vario RT: 227	Vector: 160 Vario 1: 227 Vario RT: 227	Vario 1: 227 Vario 2: 307 Vario RT: 227	Same as the primary predicate devices
Max. scan length topogram	1680 mm with table extension	1680 mm with table extension 2080 mm with table extension	1680 mm with table extension	1680 mm with table extension 2080 mm with table extension	Same as the primary predicate devices
Max. scan length Image acquisition	Max. 1600 mm with patient table extension	Max. 1600 mm with patient table extension	Max. 1600 mm with patient table extension	Max. 1600 mm with patient table extension	Same as the primary predicate devices

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalence (SE)
	SOMATOM go.Now	**SOMATOM go.Up**	**SOMATOM go.Now**	**SOMATOM go.Up**	
		Max. 2000 mm with patient table extension		Max. 2000 mm with patient table extension	
Spectral filtration	Tin Filter		Tin Filter		Same as the primary predicate devices
High Power 80	yes	yes	yes	yes	Same as the primary predicate devices
FAST 3D Camera	option for patient positioning with 3D Camera: • gantry mounted	option for patient positioning with 3D Camera: • ceiling mounted • gantry mounted	option for patient positioning with 3D Camera: • gantry mounted	option for patient positioning with 3D Camera: • ceiling mounted • gantry mounted	Same as the primary predicate devices
x-ray foot switch	Option to trigger hands-free scanning		Option to trigger hands-free scanning		Same as the primary predicate devices
Table foot switch	Option for table patient movement		Option for table patient movement		Same as the primary predicate devices
i-joystick	Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.		Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.		Same as the primary predicate devices

SIEMENS
Healthineers

Hardware property	Subject device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalence (SE)
	SOMATOM go.Now	**SOMATOM go.Up**	**SOMATOM go.Now**	**SOMATOM go.Up**	
Tablet dock	Option for mounting of the tablet on the patient table.		Option for mounting of the tablet on the patient table.		Same as the primary predicate devices
CARE Breathe	visualization of breathing instructions to support three messages in respiratory motion management: • free breathing • preparation for breath hold • breath hold itself in combination with the visualization of a countdown visual patient instruction unit is placed on the gantry front and gantry back in the gantry funnel		visualization of breathing instructions to support three messages in respiratory motion management: • free breathing • preparation for breath hold • breath hold itself in combination with the visualization of a countdown visual patient instruction unit is placed on the gantry front and gantry back in the gantry funnel		Same as the primary predicate devices
CARE 2D camera	one integrated into the gantry front and one mounted on the gantry back to monitor the patient during examination		one integrated into the gantry front and one mounted on the gantry back to monitor the patient during examination		Same as the primary predicate devices
CARE Moodlight	LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Scan		LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Radiation on		Same functionality as the primary predicate devices. In the subject devices with syngo CT VB20, the status "Radiation on" has been renamed to "Scan".

SIEMENS
Healthineers

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Now	SOMATOM go.Up	SOMATOM go.Now	SOMATOM go.Up	
Respiratory Motion management - Interfaces for respiratory gating	n.a.	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system Varian RGSC respiratory gating system • Open interface compatible respiratory gating systems • Open Online interface	n.a.	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system Varian RGSC respiratory gating system • Open interface compatible respiratory gating systems	Same as the primary predicate device, the subject device SOMATOM go.Up with software version *syngo* CT VB20 support acquisition of respiration-correlated scans. For measurement of the breathing signal of the patient, interfaces for connecting of 3rd party respiratory gating devices are offered. Introduction of new Open Online Interface.

Table 5: Comparison of technical hardware characteristics between the subject devices SOMATOM go.All and SOMATOM go.Top with software version syngo CT VB20 and the primary predicate devices SOMATOM go.All and SOMATOM go.Top with software version syngo CT VB10 (K233650).

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.All	SOMATOM go.Top	
scanner	Whole body Computed Tomography (CT) Scanner System		Whole body Computed Tomography (CT) Scanner System		Same as the primary predicate devices
System Configuration	Single Source		Single Source		Same as the primary predicate devices
Environment of Use	Professional Healthcare Facility		Professional Healthcare Facility		Same as the primary predicate devices
Generator Max. power (kW)	75		75		Same as the primary predicate devices
Detector technology	Stellar based on UFC (Ultra Fast Ceramic)		Stellar based on UFC (Ultra Fast Ceramic)		Same as the primary predicate devices
Detector volume coverage (mm)	22.4	38.4	22.4	38.4	Same as the primary predicate devices
Detector physical rows	32	64	32	64	Same as the primary predicate devices
Detector Slice width (mm)	0.7	0.6	0.7	0.6	Same as the primary predicate devices
Detector DAS channel no.	768	840	768	840	Same as the primary predicate devices

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.All	SOMATOM go.Top	
Detector Image slices	64	128	64	128	Same as the primary predicate devices
Tube technology	Athlon		Athlon		Same as the primary predicate devices
Tube kV steps	70 to 140 (in 10 kV steps)		70 to 140 (in 10 kV steps)		Same as the primary predicate devices
Tube Max. current (mA)	825		825		Same as the primary predicate devices
Tube focus	• 1.1 x 1.2 / 8° • 0.8 x 0.8 / 8°		• 1.1 x 1.2 / 8° • 0.8 x 0.8 / 8°		Same as the primary predicate devices
Tube Heat storage capacity (MHU)	7		7		Same as the primary predicate devices
Tube Cooling rate (kHU/ min)	Up to 1700		Up to 1700		Same as the primary predicate devices
Gantry Bore size	70		70		Same as the primary predicate devices
Gantry Scan FoV (cm)	50		50		Same as the primary predicate devices

SIEMENS ∴
Healthineers

Hardware property	Subject device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.All	**SOMATOM go.Top**	**SOMATOM go.All**	**SOMATOM go.Top**	
Gantry Extended FoV (cm)	70		70		Same as the primary predicate devices
Gantry Rot. time (sec)	0.33, 0.5, 1.0		0.33, 0.5, 1.0		Same as the primary predicate devices
Gantry Tilt (degree)	+/- 30° -30° to +28° with optional 307 kg patient table		+/- 30° -30° to +28° with optional 307 kg patient table		Same as the primary predicate devices
Patient table Type	Vario 1 (1600 mm) Vario 2 (2000 mm) Vario RT (1600 mm) with table extension		Vario 1 (1600 mm) Vario 2 (2000 mm) Vario RT (1600 mm) with table extension		Same as the primary predicate devices
Patient table Max. weight capacity (kg)	Vario 1: 227 Vario 2: 307 Vario RT: 227		Vario 1: 227 Vario 2: 307 Vario RT: 227		Same as the primary predicate devices
Max. scan length topogram	1680 mm with table extension 2080 mm with table extension		1680 mm with table extension 2080 mm with table extension		Same as the primary predicate devices
Max. scan length Image acquisition	Max. 1600 mm with patient table extension Max. 2000 mm with patient table extension		Max. 1600 mm with patient table extension Max. 2000 mm with patient table extension		Same as the primary predicate devices

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.All	SOMATOM go.Top	SOMATOM go.All	SOMATOM go.Top	
Spectral filtration	Tin Filter	Combined Tin Filter/Split filter	Tin Filter	Combined Tin Filter/Split filter	Same as the primary predicate devices
High Power 70/ High Power 80	825 (@70 kV) 825 (@ 80 kV)		825 (@70 kV) 825 (@ 80 kV)		Same as the primary predicate devices
FAST 3D Camera	option for patient positioning with FAST 3D Camera: • ceiling mounted • gantry mounted		option for patient positioning with FAST 3D Camera: • ceiling mounted • gantry mounted		Same as the primary predicate devices
x-ray foot switch	Option to trigger hands-free scanning		Option to trigger hands-free scanning		Same as the primary predicate devices
Table foot switch	Option for table patient movement		Option for table patient movement		Same as the primary predicate devices
i-joystick	Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.		Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.		Same as the primary predicate devices
Tablet dock	Option for mounting of the tablet on the patient table.		Option for mounting of the tablet on the patient table.		Same as the primary predicate devices
CARE Breathe	visualization of breathing instructions to support three messages in respiratory motion management:		visualization of breathing instructions to support three messages in respiratory motion management:		Same as the primary predicate devices

Hardware property	Subject device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.All	**SOMATOM go.Top**	**SOMATOM go.All**	**SOMATOM go.Top**	
	• free breathing • preparation for breath hold • breath hold itself in combination with the visualization of a countdown visual patient instruction unit is placed on the gantry front and gantry back in the gantry funnel		• free breathing • preparation for breath hold • breath hold itself in combination with the visualization of a countdown visual patient instruction unit is placed on the gantry front and gantry back in the gantry funnel		
CARE 2D camera	one integrated into the gantry front and one mounted on the gantry back to monitor the patient during examination		one integrated into the gantry front and one mounted on the gantry back to monitor the patient during examination		Same as the primary predicate devices
CARE Moodlight	LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Scan		LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Radiation on		Same functionality as the primary predicate devices In the subject devices with syngo CT VB20, the status "Radiation on" has been renamed to "Scan".
Respiratory Motion management - Interfaces for respiratory gating	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system • Varian RGSC respiratory gating system		acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system • Varian RGSC respiratory gating system		Same as the primary predicate devices, the subject devices SOMATOM go.All and SOMATOM go.Top with software version *syngo* CT VB20 support acquisition of respiration-correlated scans.

SIEMENS ⦿⦿⦿
Healthineers ⦿⦿

Hardware property	Subject device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.All	**SOMATOM go.Top**	**SOMATOM go.All**	**SOMATOM go.Top**	
	• Open interface compatible respiratory gating systems • Open Online interface		• Open interface compatible respiratory gating systems		For measurement of the breathing signal of the patient, interfaces for connecting of 3rd party respiratory gating devices are offered. Introduction of new Open Online Interface.

Table 6: Comparison of technical hardware characteristics between the subject devices SOMATOM go.Sim and SOMATOM go.Open Pro with software version syngo CT VB20 and the primary predicate devices SOMATOM go.Sim and SOMATOM go.Open Pro with software version syngo CT VB10 (K233650).

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Sim	SOMATOM go.Open Pro	SOMATOM go.Sim	SOMATOM go.Open Pro	
scanner	Whole body Computed Tomography (CT) Scanner System		Whole body Computed Tomography (CT) Scanner System		Same as the primary predicate devices
System Configuration	Single Source		Single Source		Same as the primary predicate devices
Environment of Use	Professional Healthcare Facility		Professional Healthcare Facility		Same as the primary predicate devices
Generator Max. power (kW)	75		75		Same as the primary predicate devices
Detector technology	Stellar based on UFC (Ultra Fast Ceramic)		Stellar based on UFC (Ultra Fast Ceramic)		Same as the primary predicate devices
Detector volume coverage (mm)	19.2	38.4	19.2	38.4	Same as the primary predicate devices
Detector physical rows	32	64	32	64	Same as the primary predicate devices
Detector Slice width (mm)	0.6	0.6	0.6	0.6	Same as the primary predicate devices

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Sim	SOMATOM go.Open Pro	SOMATOM go.Sim	SOMATOM go.Open Pro	
Detector DAS channel no.	920	920	920	920	Same as the primary predicate devices
Detector Image slices	64	128	64	128	Same as the primary predicate devices
Tube technology	Athlon		Athlon		Same as the primary predicate devices
Tube kV steps	70 to 140 (in 10 kV steps)		70 to 140 (in 10 kV steps)		Same as the primary predicate devices
Tube Max. current (mA)	825		825		Same as the primary predicate devices
Tube focus	• 1.1 x 1.2 / 7° • 0.8 x 0.8 / 7°		• 1.1 x 1.2 / 7° • 0.8 x 0.8 / 7°		Same as the primary predicate devices
Tube Heat storage capacity (MHU)	7		7		Same as the primary predicate devices
Tube Cooling rate (kHU/ min)	Up to 1700		Up to 1700		Same as the primary predicate devices

SIEMENS ·.·
Healthineers

Hardware property	Subject device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Sim	**SOMATOM go.Open Pro**	**SOMATOM go.Sim**	**SOMATOM go.Open Pro**	
Gantry Bore size	85		85		Same as the primary predicate devices
Gantry Scan FoV (cm)	60		60		Same as the primary predicate devices
Gantry Extended FoV (cm)	85		85		Same as the primary predicate devices
Gantry Rot. time (sec)	0.35, 0.5, 1.0		0.35, 0.5, 1.0		Same as the primary predicate devices
Gantry Tilt (degree)	-30° to +25°		-30° to +25°		Same as the primary predicate devices
Patient table Type	Vario 2 (2000 mm) Vario RT (1600 mm) with table extension		Vario 2 (2000 mm) Vario RT (1600 mm) with table extension		Same as the primary predicate devices
Patient table Max. weight capacity (kg)	Vario 2: 307 Vario RT: 227		Vario 2: 307 Vario RT: 227		Same as the primary predicate devices
Max. scan length topogram	1680 mm with table extension 2080 mm with table extension		1680 mm with table extension 2080 mm with table extension		Same as the primary predicate devices

SIEMENS
Healthineers

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Sim	**SOMATOM go.Open Pro**	**SOMATOM go.Sim**	**SOMATOM go.Open Pro**	
Max. scan length Image acquisition	Max. 1600 mm with patient table extension Max. 2000 mm with patient table extension		Max. 1600 mm with patient table extension Max. 2000 mm with patient table extension		Same as the primary predicate devices
Spectral filtration	Tin Filter	Combined Tin Filter/Split filter	Tin Filter	Combined Tin Filter/Split filter	Same as the primary predicate devices
High Power 70/ High Power 80	825 (@70 kV) 825 (@ 80 kV)		825 (@70 kV) 825 (@ 80 kV)		Same as the primary predicate devices
FAST 3D Camera	option for patient positioning with FAST 3D Camera: • ceiling mounted		option for patient positioning with FAST 3D Camera: • ceiling mounted		Same as the primary predicate devices
CARE Moodlight	LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Scan		LED lights integrated on the gantry front cover indicating[9]: • System startup • Scan countdown • Radiation on		CARE Moodlight is introduced for SOMATOM go.Sim and SOMATOM go.Open Pro In the subject devices with *syngo* CT VB20, the status

[9] Added based on non-filing documentation (document-to-file) after the clearance of K233650. The modification has been considered as minor modification to the system and do not change the indications for use nor do significantly affect the safety and effectiveness of the device, hence non-filing documentation.

SIEMENS
Healthineers

Hardware property	Subject device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB20		Primary predicate device SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Sim	SOMATOM go.Open Pro	SOMATOM go.Sim	SOMATOM go.Open Pro	
					"Radiation on" has been renamed to "Scan".
x-ray foot switch	Option to trigger hands-free scanning		Option to trigger hands-free scanning		Same as the primary predicate devices
Table foot switch	Option for table patient movement		Option for table patient movement		Same as the primary predicate devices
i-joystick	Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.		Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.		Same as the primary predicate devices
Tablet dock	Option for mounting of the tablet on the patient table.		Option for mounting of the tablet on the patient table.		Same as the primary predicate devices
CARE Breathe	n.a.		n.a.		Same as the primary predicate devices
CARE 2D camera	Patient observation camera integrated on gantry front		Patient observation camera integrated on gantry front		Same as the primary predicate devices
Respiratory Motion management - Interfaces for respiratory gating	acquisition of respiration-correlated scans supported Interface connectors for:		acquisition of respiration-correlated scans supported Interface connectors for:		Same as the primary predicate devices, the subject devices SOMATOM go.Sim and SOMATOM go.Open Pro with software version *syngo* CT

Hardware property	Subject device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM go.Sim	**SOMATOM go.Open Pro**	**SOMATOM go.Sim**	**SOMATOM go.Open Pro**	
	• Anzai respiratory gating system • Varian RGSC respiratory gating system • Open interface compatible respiratory gating systems • Open Online interface		• Anzai respiratory gating system • Varian RGSC respiratory gating system • Open interface compatible respiratory gating systems		VB20 support acquisition of respiration-correlated scans. For measurement of the breathing signal of the patient, interfaces for connecting of 3rd party respiratory gating devices are offered. Introduction of new Open Online Interface.

SIEMENS
Healthineers

Table 7: Comparison of technical hardware characteristics between the subject device SOMATOM Pro.Pulse with software version syngo CT VB20 and the predicate devices SOMATOM Pro.Pulse (K232206) and SOMATOM go.Top (K233650) with software version syngo CT VB10 (K232206).

Hardware property	Subject device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB20	Primary predicate device SOMATOM go.Top[10] with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
scanner	Whole body Computed Tomography (CT) Scanner System	Whole body Computed Tomography (CT) Scanner System	Whole body Computed Tomography (CT) Scanner System	Same as the primary and the secondary predicate device
System Configuration	Dual Source	Single Source	Dual Source	Same as the secondary predicate device
Environment of Use	Professional Healthcare Facility	Professional Healthcare Facility	Professional Healthcare Facility	Same as the primary and the secondary predicate device
Generator Max. power (kW)	150 (2 x 75)	75	150 (2 x 75)	Same as the secondary predicate device
Detector technology	Stellar detector based on Multislice UFC (Ultra Fast Ceramic)	Stellar detector based on Multislice UFC (Ultra Fast Ceramic)	Stellar detector based on Multislice UFC (Ultra Fast Ceramic)	Same as the primary and the secondary predicate device
Detector volume coverage	38.4 mm	38.4 mm	38.4 mm	Same as the primary and secondary predicate device
Detector physical rows	2 x 64	64	2 x 64	Same as the primary and the secondary predicate device

---

[10] The primary predicate device of this eSTAR submission is the SOMATOM go. Platform with *syngo* CT VB10 (K233650). K233650 is a bundle 510(k) which the SOMATOM go.Top is part of.

SIEMENS ∴
Healthineers

Hardware property	Subject device **SOMATOM Pro.Pulse** with SOMARIS/10 *syngo* CT VB20	Primary predicate device **SOMATOM go.Top[10]** with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device **SOMATOM Pro.Pulse** with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
Detector Slice width	0.6 mm	0.6 mm	0.6 mm	Same as the primary and secondary predicate device
Detector DAS channel no.	840 (detector A) 600 (detector B)	840	840 (detector A) 600 (detector B)	Same as the secondary predicate device
Detector Image slices	2 x 128 (with Interleaved Volume Reconstruction, IVR) 2 x 384 (reconstructed slices)	128 (with Interleaved Volume Reconstruction, IVR) 384 (reconstructed slices)	2 x 128 (with Interleaved Volume Reconstruction, IVR) 2 x 384 (reconstructed slices)	Same as the secondary predicate device
Tube technology	2 x Athlon® DS X-ray tube	Athlon® X-ray tube	2 x Athlon® DS X-ray tube	Same as the secondary predicate device.
Tube collimator	Tube collimator DS4-A, DS4-B • Equivalent to 0.5 mm Al in the isocenter • 1 mm Al with cardio wedge	Tube collimator • Equivalent to 0.5 mm Al in the isocenter • 1 mm Al with cardio wedge	Tube collimator DS4-A, DS4-B • Equivalent to 0.5 mm Al in the isocenter • 1 mm Al with cardio wedge	Same as the secondary predicate device.
Tube kV steps	70–140 kV in 10 kV steps	70–140 kV in 10 kV steps	70–140 kV in 10 kV steps	Same as the primary and the secondary predicate device
Tube Max. current	Single Source: 13-825 mA Dual Source: 26-1650 mA	Standard range: 13 – 825 mA	Single Source: 13-825 mA Dual Source: 26-1650 mA	Same as the secondary predicate device.

Hardware property	Subject device **SOMATOM Pro.Pulse** with SOMARIS/10 *syngo* CT VB20	Primary predicate device **SOMATOM go.Top**[10] with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device **SOMATOM Pro.Pulse** with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
Tube focus	• 0.8 × 0.8 / 7° • 1.0 × 1.2 / 7°	• 0.8 × 0.8 / 7° • 1.0 × 1.2 / 7°	• 0.8 × 0.8 / 7° • 1.0 × 1.2 / 7°	Same as the primary and the secondary predicate device.
Tube Heat storage capacity	2 x 7.0 MHU	7.0 MHU	2 x 7.0 MHU	Same as the primary and the secondary predicate device.
Tube Cooling rate (MHU/ min)	up to 1.7	up to 1.7	up to 1.7	Same as the primary and the secondary predicate device.
Gantry Bore size	70	70	70	Same as the primary and the secondary predicate device
Gantry Scan FoV (cm)	50	50	50	Same as the primary and the secondary predicate device
Gantry Extended FoV (cm)	70	70	70	Same as the primary and the secondary predicate device
Gantry Rot. time (sec)	0.33 (optional), 0.5, 1.0	0.33 (optional), 0.5, 1.0	0.33 (optional), 0.5, 1.0	Same as the primary and the secondary predicate device
Gantry Tilt (degree)	n.a.	± 30°	n.a.	Same as the secondary predicate device.
Maximum temporal	86 ms (mono-segment)	165 ms (mono-segment)	86 ms (mono-segment)	Same as the secondary predicate device

Hardware property	Subject device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB20	Primary predicate device SOMATOM go.Top[10] with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
resolution in ECG gated or triggered examination (ms)	43 ms (bi-segment)	82.5 ms (bi-segment)	43 ms (bi-segment)	
Maximum scan speed at pitch (mm/s at pitch x)	372 mm/s at pitch 3.2	175 mm/s at pitch 1.5	372 mm/s at pitch 3.2	Same as the secondary predicate device
Patient table Type	Vario 2 (2000 mm) Vario 2.D (2000 mm)	Vario1 (1600 mm) Vario RT (1600 mm) Vario 2 (2000mm)	Vario 2 (2000 mm) Vario 2.D (2000 mm)	Same as the secondary predicate device.
Patient table Max. weight capacity (kg)	307	227 307	307	Same as the secondary predicate device.
Max. scan length topogram	2080 mm with table extension	1680 mm with table extension 2080 mm with table extension	2080 mm with table extension	Same as the secondary predicate device.
Max. scan length Image acquisition	Max. 2000 mm with patient table extension	Max. 1600 mm with patient table extension Max. 2000 mm with patient table extension	Max. 2000 mm with patient table extension	Same as the secondary predicate device.

Hardware property	Subject device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB20	Primary predicate device SOMATOM go.Top[10] with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
Spectral filtration	Tin Filter	Combined Tin Filter / Split Filter	Tin Filter	Same as the secondary predicate device
FAST 3D Camera	option for patient positioning with FAST 3D Camera: • Ceiling mounted • Gantry mounted	option for patient positioning with FAST 3D Camera: • ceiling mounted • gantry mounted	option for patient positioning with FAST 3D Camera: • Ceiling mounted • Gantry mounted	Same as the primary and the secondary predicate device
High Power 70/ High Power 80	up to 825 mA (@70 kV)/ up to 825 mA (@80 kV)	up to 825 mA (@70 kV)/ up to 825 mA (@80 kV)	up to 825 mA (@70 kV)/ up to 825 mA (@80 kV)	Same as the primary and the secondary predicate device
x-ray foot switch	Option to trigger hands-free scanning	Option to trigger hands-free scanning	Option to trigger hands-free scanning	Same as primary and the secondary predicate device
Table foot switch	Option for table patient movement	Option for table patient movement	Option for table patient movement	Same as the primary and the secondary predicate device
i-joystick	Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.	Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.	Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.	Same as the primary and the secondary predicate device
Tablet dock	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.	Same as the primary and the secondary predicate device

SIEMENS ·
Healthineers

Hardware property	Subject device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB20	Primary predicate device SOMATOM go.Top[10] with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
CARE 2D camera	one integrated into the gantry front and one mounted on the gantry back to monitor the patient during examination	one integrated into the gantry front and one mounted on the gantry back to monitor the patient during examination	one integrated into the gantry front and one mounted on the gantry back to monitor the patient during examination	Same as the primary and the secondary predicate device
CARE Moodlight	LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Scan	LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Radiation on	LED lights integrated on the gantry front cover indicating: • System startup • Scan countdown • Radiation on	Same as the primary and the secondary predicate device. In the subject device with *syngo* CT VB20, the status "Radiation on" has been renamed to "Scan".
Moodlight	• Gantry ring Moodlight: ambient light during examination. • CARE Funnel Light: ambient light which illuminates the gantry funnel	• Gantry ring Moodlight: ambient light during examination.	• Gantry ring Moodlight: ambient light during examination. • CARE Funnel Light: ambient light which illuminates the gantry funnel	Same as the secondary predicate device

SIEMENS ∴·.
Healthineers ∴·.

Table 8: Comparison of software characteristics between the subject devices with software version syngo CT VB20 and the predicate devices with software version syngo CT VB10 (K233650 and K232206).

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
Operating System	Windows based SOMARIS/10 *syngo* CT VB20 Note: the short version *syngo* CT VB20 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VB20 Note: the short version *syngo* CT VB20 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VB10 Note: the short version *syngo* CT VB10 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VB10 Note: the short version *syngo* CT VB10 is also used as labeling information	Software version upgraded due to new functionalities.
Workplace	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction System (IRS)	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction System (IRS)	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction System (IRS)	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction System (IRS)	Same as the primary and secondary predicate devices

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	2nd workplace option named as "myExam Satellite" with Remote Recon function	2nd workplace option named as "myExam Satellite" with Remote Recon function	2nd workplace option named as "myExam Satellite" with Remote Recon function	2nd workplace option named as "myExam Satellite" with Remote Recon function	
Standard system software	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network	Same as the primary and secondary predicate devices
Detector firmware	Stellar detector firmware supported	Stellar detector firmware supported	Stellar detector firmware supported	Stellar detector firmware supported	Same as the primary and secondary predicate devices

SIEMENS
Healthineers

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
Teamplay	Support of Teamplay protocols	Support of Teamplay protocols	Support of Teamplay protocols	Support of Teamplay protocols	Same as the primary and secondary predicate devices
Protocols	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocols that allow scanning with support of an external respiratory gating system	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocols supporting contrast bolus-triggered data acquisition	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocols that allow scanning with support of an external respiratory gating system	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocols supporting contrast bolus-triggered data acquisition	SOMATOM go. Platform: Same as the primary predicate devices SOMATOM Pro.Pulse:

SIEMENS ⋯⋯
Healthineers ⋯⋯

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	• Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition (TwinBeam DE and TwinSpiral DE) • Dynamic imaging (Flex 4D Spiral)	• Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Dynamic imaging (Flex 4D Spiral) • interventional scan protocols (scan modes: i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution	• Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition (TwinBeam DE and TwinSpiral DE) • Dynamic imaging (Flex 4D Spiral)	• Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Dynamic imaging (Flex 4D Spiral) • interventional scan protocols (scan modes: i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution	Same as the secondary predicate device

SIEMENS
Healthineers

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	• Protocols supporting CT Intervention (scan modes: 2D i-sequence, 3D i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning • Protocols for DirectBreathhold	• Turbo Flash Spiral • various i-spiral and i-sequence scan protocols (applying different scanning parameters such as different slice thicknesses, kV settings or reconstructions kernels to support different clinical scenarios) and using features like iMAR, CARE Dose4D and CARE kV	• Protocols supporting CT Intervention (scan modes: i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning • Protocols for DirectBreathhold	• Turbo Flash Spiral • various i-spiral and i-sequence scan protocols (applying different scanning parameters such as different slice thicknesses, kV settings or reconstructions kernels to support different clinical scenarios) and using features like iMAR, CARE Dose4D and CARE kV	

SIEMENS ··
Healthineers ··

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
		• TwinkV (Dual Source Dual Energy acquisition)		• TwinkV (Dual Source Dual Energy acquisition)	
Advanced Reconstruction	Recon&GO: - Spectral Recon (Dual Energy Reconstruction including Virtual Unenhanced, Monoenergetic plus) - DE SPP (Spectral Post-Processing) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual	Recon&GO: - Spectral Recon (Dual Energy Reconstruction including None, low (L3D) and high (H3D) energy images) - DE SPP (Spectral Post-Processing) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual	Recon&GO: - Spectral Recon (Dual Energy Reconstruction including Virtual Unenhanced, Monoenergetic plus) - DE SPP (Spectral Post-Processing) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual	Recon&GO: - Spectral Recon (Dual Energy Reconstruction including None, low (L3D) and high (H3D) energy images) - DE SPP (Spectral Post-Processing) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual	SOMATOM go. Platform: Same as the primary predicate devices SOMATOM Pro.Pulse: Same as the secondary predicate device

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	
Image viewing	CT View&GO offers: - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI)	CT View&GO offers: - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI)	CT View&GO offers: - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI)	CT View&GO offers: - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI)	Same as the primary and the secondary predicate devices

SIEMENS ·.·:
Healthineers ·.·

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	- Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	- Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	- Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	- Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	
Software interface	• Recon&GO Inline Results Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices in their own right.	• Recon&GO Inline Results Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices in their own right.	• Recon&GO Inline Results Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices in their own right.	• Recon&GO Inline Results Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices in their own right.	In software version *syngo* CT VB20, the subject devices introduce plug-in interface for the stand alone software application myAblation Guide.

SIEMENS ∴.
Healthineers ∴.

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	• software interfaces for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone Advanced Visualization Application software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in	• software interfaces for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone Advanced Visualization Application software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in	• software interfaces for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone Advanced Visualization Application software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in	• software interfaces for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone Advanced Visualization Application software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in	

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners. • Plug-in interface for myAblation Guide	the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners. • Plug-in interface for myAblation Guide	the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners.	the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners.	
Cybersecurity	IT Hardening	IT Hardening	IT Hardening	IT Hardening	Same as the primary and the secondary predicate devices
HD FoV	HD FoV 4.0	HD FoV 4.0	HD FoV 4.0	HD FoV 4.0	The subject devices

SIEMENS ....
Healthineers ....

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	HD FoV 5.0[11]				SOMATOM go. Sim and SOMATOM go.Open Pro with *syngo* CT VB20 support a new generation of extended field of view reconstruction algorithm: HD FoV 5.0.

[11] HD FoV 5.0: In software version *syngo* CT VB20, this version of HD FoV is available for SOMATOM go.Sim and SOMATOM go.Open Pro only.

SIEMENS
Healthineers

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
Standard technologies	• FAST technologies • CARE technologies • GO technologies	• FAST technologies • CARE technologies • GO technologies	• FAST technologies • CARE technologies • GO technologies	• FAST technologies • CARE technologies • GO technologies	Same as the primary and the secondary predicate devices
Iterative Reconstruction Methods	ADMIRE iMAR SAFIRE	ADMIRE iMAR	ADMIRE iMAR SAFIRE	ADMIRE iMAR	SOMATOM go. Platform: Same as the primary predicate devices SOMATOM Pro.Pulse:

SIEMENS ·.·
Healthineers ·.·

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
					Same as the secondary predicate
Matrix sizes	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)	Same as the primary and the secondary predicate device
DirectDensity	including relative electron density, relative mass density, and stopping power ratio	including relative electron density, relative mass density, and stopping power ratio	including relative electron density, relative mass density	including relative electron density and relative mass density	Compared to the predicate devices, the subject devices with *syngo* CT VB20 support a

SIEMENS ··
Healthineers ···

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
					modified DirectDensity functionality.
Stack artifact reduced reconstruction	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations ZeeFree RT[12]: StackRecon types in	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations	ZeeFree RT is a new functionality introduced with *syngo* CT VB20 for the subject device SOMATOM go.Open Pro.

---

[12] ZeeFree RT: In software version *syngo* CT VB20, ZeeFree RT is available for SOMATOM go.Open Pro only.

SIEMENS :·.·.
Healthineers ·:··

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	respiratory-related examinations				
Oncology exchange	transfer of prescription information from the ARIA Oncology Information System (OIS) to the CT scanner	transfer of prescription information from the ARIA Oncology Information System (OIS) to the CT scanner	n.a.	n.a.	New functionality introduced with *syngo* CT VB20.
DirectSetup Notes	patient and accessory setup documentation in the Scan&GO workflow	patient and accessory setup documentation in the Scan&GO workflow	n.a.	n.a.	The subject devices SOMATOM go. Platform CT scanner systems are enabled to support DirectSetup Notes.

SIEMENS ∴∴
Healthineers ∴∴

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now SOMATOM go.Up SOMATOM go All SOMATOM go.Top SOMATOM go.Sim SOMATOM go.Open Pro	SOMATOM Pro.Pulse	SOMATOM go.Now SOMATOM go.Up SOMATOM go All SOMATOM go.Top SOMATOM go.Sim SOMATOM go.Open Pro	SOMATOM Pro.Pulse	
					DirectSetup Notes was cleared in K233650 for SOMATOM go.Sim and SOMATOM go.Open Pro.
FAST Integrated Workflow (FAST 3D Camera)	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction • Collision Indication	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction • Collision Indication	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction	Compared to the predicate devices, the FAST 3D Camera of the subject devices supports in *syngo* CT VB20 a Collision indication and

SIEMENS ∴∴
Healthineers ∴∴∴

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	• Centerline/ Grid Overlay	• Centerline/ Grid Overlay			Centerline/Grid Overlay function.
FAST Planning	detects globally used scan and recon ranges from the topogram image additional body regions: - Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung	detects globally used scan and recon ranges from the topogram image additional body regions: - Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung	detects globally used scan and recon ranges from the topogram image	detects globally used scan and recon ranges from the topogram image	As the primary and secondary devices, the subject devices with *syngo* VB20 support FAST Planning functionality with wide range of body regions. In *syngo* CT VB20, FAST Planning has been extended

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
	- Extremities – Both knees	- Extremities – Both knees			with additional body regions.
Eco Power Mode	reduce the energy consumption during idle times.[13]	reduce the energy consumption during idle times.	n.a.	n.a.	New feature introduced with *syngo* CT VB20 of the subject devices.
myExam Contrast	exchange of contrast injection parameters, scan and patient parameters	exchange of contrast injection parameters, scan and patient parameters	n.a.	n.a.	New feature introduced with *syngo* CT VB20.

---

[13] SOMATOM go.Now and SOMATOM go.Up do not support Eco Power Mode.

Software property	Subject device with SOMARIS/10 *syngo* CT VB20		Primary predicate device with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device with SOMARIS/10 *syngo* CT VB10 (K232206)	Assessment of the substantial equivalency (SE)
	SOMATOM go.Now **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	**SOMATOM go.Now** **SOMATOM go.Up** **SOMATOM go All** **SOMATOM go.Top** **SOMATOM go.Sim** **SOMATOM go.Open Pro**	**SOMATOM Pro.Pulse**	
Breathhold technique	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations. DirectBreathold: externally triggered workflow to start a spiral scan by receiving a trigger signal from an external gating device.	n.a.	Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations. DirectBreathold: externally triggered workflow to start a spiral scan by receiving a trigger signal from an external gating device.	n.a.	SOMATOM go. Platform: Same as the primary predicate devices SOMATOM Pro.Pulse does not support DirectBreathhold

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 SOMATOM go. Platform and SOMATOM Pro.Pulse with *syngo* CT VB20 are comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the primary predicate devices.

VIII. Performance Data

Non-Clinical Testing

Non-clinical testing, (integration and functional) including phantom tests were conducted for the SOMATOM go. Platform and SOMATOM Pro.Pulse CT scanner systems with *syngo* CT VB20 during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

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

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

System Validation test:
- Acceptance test (workflow and user manual test)
- Legal and Regulatory test

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

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

Bench testing:

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 9 below.

Table 9: Non-clinical performance testing (bench testing).

Feature/Non-clinical supportive testing	Bench Testing performed
FAST 3D Camera/ FAST Integrated Workflow	The FAST 3D camera sub-features FAST Isocentering, FAST Range, and FAST Direction have been optimized using additional data from adults and adolescence patients. The bench test evaluates and compares the accuracy of the three sub-features in software version *syngo* CT VB20 to the accuracy of the predicate devices with *syngo* CT VB10. The objectives of the bench tests are to demonstrate that the FAST 3D camera achieves comparable or better results for both, adults and adolescents, as the predicate device for adults.

Feature/Non-clinical supportive testing	Bench Testing performed
	Overall, the subject devices with *syngo* CT VB20 delivers comparable or improved accuracy to the predicate devices with *syngo* CT VB10 predicate device for adults and extends the support to adolescents.
FAST Planning	The purpose of the test is to provide a clear reporting on the applied algorithm, its product development, validation, and verification on patient data, which enable the claims.

Objective of the test is to assess the fraction (percentage) of ranges calculated by the FAST Planning algorithm that are correct and can be applied without change. Additionally, calculation time was measured to check whether it meets interactive requirements.

The test results show that the editing actions for the scanner technician can be reduced to a minimum and that the calculation time is fast enough for interactive speed during scanning. For more than 90% of the ranges no editing action was necessary to cover standard ranges. For more than 95%, the speed of the algorithm was sufficient. |
| HD FoV 5.0 | The bench test contains a detailed description and evaluation of the new HD FoV 5. 0 algorithm for extended field of view reconstruction. Results obtained with the new HD FoV 5. 0 algorithm are compared with its predecessor, the HD FoV 4. 0 algorithm, based on physical and anthropomorphic phantoms.

In addition to the bench test, the performance of the algorithm was evaluated by board-approved radio-oncologists and medical physicists by means of retrospective blinded rater study.

This comparison is conducted to demonstrate that the HD FoV 5. 0 algorithm is as safe and effective as the HD FoV 4. 0 algorithm. |
| Flex 4D Spiral | The performed bench test report describes the technical background of Flex 4D Spiral and its functionalities with SOMATOM CT scanners, demonstrate the proper function of those, and assess the image quality of Flex 4D Spiral. |
| ZeeFree RT | The bench test evaluates the performance of the ZeeFree RT reconstruction. The objectives of the tests are to demonstrate that compared to the Standard reconstruction, ZeeFree RT

- introduces no relevant errors in terms of CT values and noise levels measured in a homogeneous water phantom, *and*
- introduces no relevant errors in terms of CT values measured in a phantom with tissue-equivalent inserts, even in the presence of metals and in combination with the iMAR algorithm, *and*
- introduces no relevant geometrical distortions in a static torso phantom, *and* |

Feature/Non-clinical supportive testing	Bench Testing performed
	• introduces no relevant deteriorations of the position or shape of a dynamic thorax phantom when moving a spherical shape according to regular, irregular, and patient breathing motion. In addition to the bench tests, the performance of the algorithm was evaluated by board-approved radio-oncologists and medical physicists by means of retrospective blinded rater studies of respiratory 4D CT examinations performed at two institutions. The bench test results show that the ZeeFree RT reconstruction • can successfully be applied to 4D respiratory-gated sequence images (Direct i4D), *and* • enables the optional reconstruction of stack artefact corrected images, which reduce the strength of misalignment artefacts, if such stack alignment artefacts are identified in non-corrected standard images, *and* • does not introduce relevant new artefacts, which were previously not present in the non-corrected standard reconstruction, *and* • does not affect CT values and noise levels in a homogenous water phantom outside of stack-transition areas compared to the non-corrected standard reconstruction, *and* • can be successfully applied in combination with metal artifact correction (iMAR) and does not introduce new artifacts, which were previously not present in the non-corrected standard reconstruction, even in presence of metals, *and* • can be successfully applied to phantom data if derived from a suitable motion phantom demonstrating its correct technical function on the tested device, *and* • is independent from the physical detector width of the acquired data. By design, input images for the correction part of the algorithm are independent of kernel, slice thickness and increment since those parameters are fixed.
DirectDensity	The test results show for the iBHC variants Artificial120, eDDensity, mDDensity and StoppingPowerRatio a reduced dependence on tube voltage and filtration compared to the corresponding quantitative kernel (Qr) with iBHC Bone for non-water-like tissues, such as adipose and bone. Furthermore, the iBHC variants Artificial120, eDDensity, mDDensity and StoppingPowerRatio generate image value closely aligned with the respective material properties. In conclusion, the feature DirectDensity at any kV has been validated for the release Som/X VB20 on all supported SOMATOM CT scanner models

A list of recognized consensus standards and general use consensus standards considered for the subject devices is provided as Table 10 and Table 11 below.

Table 10: Recognized Consensus Standards.

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
12/18/2023	12-352	NEMA	PS 3.1 - 3.20 2023e	Digital Imaging and Communications in Medicine (DICOM) Set
07/06/2020	12-325	NEMA	XR 25-2019	Computed Tomography Dose Check
07/06/2020	12-330	NEMA	XR 28-2018	Supplemental Requirements for User Information and System Function Related to Dose in CT
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 and constancy tests - Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
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
06/07/2021	12-336	IEC	60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	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	12-302	IEC	60601-2-44 Edition 3.2: 2016	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				essential performance of x-ray equipment for computed tomography
12/23/2019	5-125	ANSI AAMI ISO	14971: 2019	Medical devices - Applications of risk management to medical devices
		ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
01/14/2019	13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
		IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
05/30/2022	19-46	ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
12/21/2020	19-36	ANSI AAMI IEC	60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
		IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
07/06/2020	5-129	ANSI AAMI IEC	62366-1:2015+AMD1:2020 (Consolidated Text)	Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
		IEC	62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
07/09/2014	12-273	IEC	60825-1 Edition 2.0 2007-03	Safety of laser products - Part 1: Equipment classification, and requirements
12/21/2020	5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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
12/20/2021	12-341	IEC	62563-1 Edition 1.2 2021-07 CONSOLIDATED VERSION	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods

Table 11: 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+A2:2020	Medical electrical equipment - part 1: general requirements for	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 &

Standard Developing Organization	Standard Designation Number and Date	Title of Standard	How was Standard Used
		basic safety and essential performance	A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
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 12 below.

Table 12: FDA Guidance Document and Effective Date.

FDA Guidance Document	Issue date
User Fees and Refunds for Premarket Notification Submissions (510(k)s): Guidance for Industry and Food and Drug Administration Staff	10/05/2022
Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff	04/21/2022
Electronic Submission Template for Medical Device 510(k) Submissions	10/2/2023
Deciding When to Submit a 510(k) for a Change to an Existing Device	10/25/2017
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	07/28/2014
Content of Premarket Submissions for Software Contained in Medical Devices	06/14/2023
Off-The-Shelf Software Use in Medical Devices	09/27/2019
Applying Human Factors and Usability Engineering to Medical Devices	02/03/2016
Pediatric Information for X-ray Imaging Device Premarket Notifications	11/28/2017
Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	09/27/2023
Electromagnetic Compatibility (EMC) of Medical Devices	06/06/2022
Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices	09/06/2017

SIEMENS
Healthineers

FDA Guidance Document	Issue date
Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices	09/14/2018

Verification and Validation

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.

Wireless Coexistence Testing

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 iPad 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 SOMATOM go. Platform and SOMATOM Pro.Pulse 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 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.

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.

IX. Conclusions

Verification and validation and phantom testing were performed. The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrates that the subject devices SOMATOM go. Platform and SOMATOM Pro.Pulse CT scanner systems with software version *syngo* CT VB20 perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM go. Platform and SOMATOM Pro.Pulse CT scanner systems with software version *syngo* CT VB20 with the described modifications performs comparably to the predicate devices currently marketed for the same intended use. The conclusion drown from the non-clinical tests demonstrates that the subject devices are as safe, as effective, and perform as well as or better than the predicate devices.