March 20, 2026

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

Re: K253574
Trade/Device Name: SOMATOM X.cite; SOMATOM X.ceed
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 17, 2026
Received: February 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253574

Please provide the device trade name(s).

SOMATOM X.cite;
SOMATOM X.ceed

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253574

510(k) Summary
for

SOMATOM X. Platform CT Scanner Systems

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.

Submitter Contact Person:
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II. Device Name and Classification

Table 1: Subject Device Names

Product Name	Trade Name
SOMATOM X.cite	SOMATOM X.cite
SOMATOM X.ceed	SOMATOM X.ceed

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 X. 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 go. Platform CT Scanner Systems with SOMARIS/10 *syngo* CT VB20 software
510(k) Number:	K250822
Clearance Date:	July 3, 2025

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 primary predicate devices SOMATOM X.cite, SOMATOM X.ceed, and the CT scanner systems SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro.

K250822 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, and SOMATOM Pro.Pulse.

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:

SOMATOM X. Platform CT scanner systems:

- SOMATOM X.cite
- SOMATOM X.ceed

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

The subject devices SOMATOM X. Platform CT scanner systems with SOMARIS/10 syngo CT VB20 are Computed Tomography X-ray Systems which feature one continuously rotating tube-detector system and function according to the fan beam principle (single source). The SOMATOM X. Platform CT scanner systems with software SOMARIS/10 syngo CT VB20 produces 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 GmbH 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 platform software for SOMATOM X. Platform, SOMARIS/10 *syngo* CT VB20, is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The software platform provides 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.

Software version SOMARIS/10 *syngo* CT VB20 will be offered ex-factory and as an optional upgrade for the applicable existing SOMATOM X. Platform 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*.

* 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 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.

Comparison:

The subject device Indications for Use is the exact same as the primary and the secondary predicate's Indications for Use (K233650). 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.

The SOMATOM X. Platform 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 X. Platform 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. 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 X. Platform 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
- 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/myNeedle Laser)
- 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
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.

The subject devices SOMATOM X. Platform 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 X.cite and SOMATOM X.ceed (SOMATOM X. Platform) with software version SOMARIS/10 syngo CT VB20 compared to the predicate devices.

	Technological property	**HW/SW change**	**Subject devices**	**Predicate devices**	
			SOMATOM X. Platform with *syngo* CT VB20	**SOMATOM X. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM go. Platform** with syngo CT VB20 (K250822)
1.	CARE Moodlight	HW/SW	**enabled** (same as in K250822)	n.a.	cleared
2.	Interfaces for respiratory gating systems – Open Online Interface	HW	**enabled** (same as in K250822)	n.a.[1]	cleared
3.	Eco Power Mode	HW/SW	**enabled** (same as in K250822)	n.a.	cleared
4.	FAST 3D Camera/ FAST Integrated Workflow	SW	**enabled**[2] (same as in K250822)	cleared	cleared
5.	Oncology Exchange	SW	**enabled** (same as in K250822)	n.a.	cleared
6.	DirectSetup Notes	SW	**enabled**	n.a.	cleared

[1] The primary predicate devices SOMATOM X. Platform with software version *syngo* CT VB10 (K233650) support interfaces for respiratory gating with exception of Open Online interface. Open Online interface is now introduced with the subject devices, and it is same as cleared in the secondary predicate devices SOMATOM go. Platform with software version *syngo* CT VB20 (K250822).

[2] The subject devices SOMATOM X. Platform with software version *syngo* CT VB20 support FAST 3D Camera/ FAST Integrated workflow, which was cleared with the primary predicate devices with software version *syngo* CT VB20 (K233650). With software version *syngo* CT VB20, retrained FAST 3D Camera algorithms, collision indication, and Centerline/Grid Overlay are introduced. This modification is same as already cleared in the secondary predicate devices SOMATOM go. Platform with software version *syngo* CT VB20 (K250822).

	Technological property	HW/SW change	Subject devices	Predicate devices	
			SOMATOM X. Platform with *syngo* CT VB20	**SOMATOM X. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM go. Platform** with syngo CT VB20 (K250822)
			(same as in K250822)		
7.	FAST Planning	SW	**enabled**[3] (same as in K250822)	cleared	cleared
8.	myExam Companion – myExam Compass/myExam Cockpit	SW	**enabled**[4] (same as in K250822)	cleared	cleared
9.	HD FoV 5.0	SW	**enabled** (same as in K250822)	n.a.	cleared
10.	CT guided intervention – myAblation Guide interface	SW	**enabled** (same as in K250822)	n.a.	cleared
11.	Flex 4D Spiral	SW	**modified** (same as in K233650, with exception of the modifications regarding scan range and cycle time which are	cleared	cleared

[3] The subject devices SOMATOM X. Platform with software version *syngo* CT VB20 support FAST Planning, which was cleared with the primary predicate devices with software version *syngo* CT VB20 (K233650). With software version *syngo* CT VB20, detection of additional body regions is introduced. This modification is same as already cleared in the secondary predicate devices SOMATOM go. Platform with software version *syngo* CT VB20 (K250822).

[4] The subject devices SOMATOM X. Platform with software version *syngo* CT VB20 support FAST Planning, which was cleared with the primary predicate devices with software version *syngo* CT VB20 (K233650). With software version *syngo* CT VB20, the clinical decision trees are available not only for adults but also for children. This modification is same as already cleared in the secondary predicate devices SOMATOM go. Platform with software version *syngo* CT VB20 (K250822).

	Technological property	HW/SW change	Subject devices	Predicate devices	
			SOMATOM X. Platform with *syngo* CT VB20	**SOMATOM X. Platform** with *syngo* CT VB10 (K233650)	**SOMATOM go. Platform** with syngo CT VB20 (K250822)
			introduced with *syngo* CT VB20)		
12.	ZeeFree RT	SW	**enabled** (same as in K250822)	n.a.	cleared
13.	Direct Density	SW	**enabled**[5] (same as in K250822)	cleared	cleared
14.	myExam Contrast	SW	**enabled** (same as in K250822)	n.a.	cleared

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

A tabular summary of the comparable software properties between the subject devices SOMATOM X. Platform with software version *syngo* CT VB20 and the predicate devices are listed in Table 5 later in this document (modifications are in gray shaded sections).

[5] The subject devices SOMATOM X. Platform with software version *syngo* CT VB20 support DirectDensity, which was cleared with the primary predicate devices with software version *syngo* CT VB20 (K233650). With software version *syngo* CT VB20, calculation of stopping-power ratio (Kernel St) is introduced. This modification is same as already cleared in the secondary predicate devices SOMATOM go. Platform with software version *syngo* CT VB20 (K250822).

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

Hardware property	**Subject device** **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB20		**Primary predicate device** **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		**Assessment of the substantial equivalency (SE)**
	SOMATOM X.cite	**SOMATOM X.ceed**	**SOMATOM X.cite**	**SOMATOM X.ceed**	
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)	90 kW or 105 kW	105 kW or 120 kW	90 kW or 105 kW	105 kW or 120 kW	Same as the primary predicate devices
Detector technology	Stellar^{Infinity}		Stellar^{Infinity}		Same as the primary predicate devices
Detector volume coverage	38.4 mm		38.4 mm		Same as the primary predicate devices
Detector physical rows	64		64		Same as the primary predicate devices
Detector Slice width	0.6 mm		0.6 mm		Same as the primary predicate devices
Detector DAS channel no.	840	920	840	920	Same as the primary predicate devices
Detector Image slices	128		128		Same as the primary predicate devices
Tube technology	Vectron		Vectron		Same as the primary predicate devices
Tube kV steps	70–140 kV in 10 kV steps		70–140 kV in 10 kV steps		Same as the primary predicate devices
Tube Max. current	1100 mA (for 90 kW) 1200 mA (for 105 kW)	1200 mA (for 90 kW) 1300 mA (for 105 kW)	1100 mA (for 90 kW) 1200 mA (for 105 kW)	1200 mA (for 90 kW) 1300 mA (for 105 kW)	Same as the primary predicate devices
Tube	• 0.6 x 0.7 / 8°	• 0.4 x 0.5 / 8°	• 0.6 x 0.7 / 8°	• 0.4 x 0.5 / 8°	Same as the primary predicate devices

Hardware property	Subject device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM X.cite	**SOMATOM X.ceed**	**SOMATOM X.cite**	**SOMATOM X.ceed**	
focus	• 0.8 x 1.1 / 8° • 0.6 x 0.7 / 8° • 0.8 x 1.1 / 8°		• 0.8 x 1.1 / 8° • 0.6 x 0.7 / 8° • 0.8 x 1.1 / 8°		
Tube Heat storage capacity	higher than 30 MHU		higher than 30 MHU		Same as the primary predicate devices
Tube Cooling rate	2.7 MHU / min	2.7 MHU / min	2.7 MHU / min	2.7 MHU / min	Same as the primary predicate devices
Gantry Bore size	82 cm		82 cm		Same as the primary predicate devices
Gantry Scan FoV	50 cm		50 cm		Same as the primary predicate devices
Gantry Extended FoV	81.5 cm		81.5 cm		Same as the primary predicate devices
Gantry Rot. time	0.3, 0.5, 1.0 sec	0,25, 0.3, 0.5, 1.0 sec	0.3, 0.5, 1.0 sec	0,25, 0.3, 0.5, 1.0 sec	Same as the primary predicate devices
Gantry Tilt (degree)	+/- 25 ° +/-30 ° (only with Vitus)		+/- 25 ° +/-30 ° (only with Vitus)		Same as the primary predicate devices
Patient table Type	Vario RT (1600 mm) Vitus (2000 mm) Vario 2 (2000 mm)	Vario RT (1600 mm) Vitus (2000 mm) Vario 2.D (2000 mm)	Vario RT (1600 mm) Vitus (2000 mm) Vario 2 (2000 mm)	Vario RT (1600 mm) Vitus (2000 mm) Vario 2.D (2000 mm)	Same as the primary predicate devices
Patient table Installation option	Regular installation (Vario RT, Vario 2 and Vitus): 474 mm Installation option with extended distance (Vitus):	Regular installation (Vario RT, Vario 2 and Vitus): 474 mm	Regular installation (Vario RT, Vario 2 and Vitus): 474 mm Installation option with extended distance (Vitus):	Regular installation (Vario RT, Vario 2 and Vitus): 474 mm	Same as the primary predicate devices

Hardware property	Subject device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM X.cite	**SOMATOM X.ceed**	**SOMATOM X.cite**	**SOMATOM X.ceed**	
	674 mm (474 mm + 200 mm)		674 mm (474 mm + 200 mm)		
Patient table Max. weight capacity (kg)	227 (Vario RT) 340 (Vitus) 307 (Vario 2)	227 (Vario RT) 340 (Vitus) 307 (Vario 2.D)	227 (Vario RT) 340 (Vitus) 307 (Vario 2)	227 (Vario RT) 340 (Vitus) 307 (Vario 2.D)	Same as the primary predicate devices
Max. scan length topogram	1680 mm (Vario RT) 2080 mm (Vitus) 2080 mm with table extension (Vario 2)	1680 mm (Vario RT) 2080 mm (Vitus) 2080 mm with table extension (Vario 2.D)	1680 mm (Vario RT) 2080 mm (Vitus) 2080 mm with table extension (Vario 2)	1680 mm (Vario RT) 2080 mm (Vitus) 2080 mm with table extension (Vario 2.D)	Same as the primary predicate devices
Max. scan length Image acquisition	1600 mm (Vario RT) 2000 mm (Vitus) 2000 mm (Vario 2) with table extension	1600 mm (Vario RT) 2000 mm (Vitus) 2000 mm (Vario 2.D) with table extension	1600 mm (Vario RT) 2000 mm (Vitus) 2000 mm (Vario 2) with table extension	1600 mm (Vario RT) 2000 mm (Vitus) 2000 mm (Vario 2.D) with table extension	Same as the primary predicate devices
Spectral filtration	Combined Tin Filter / Split Filter, and extra Tin Filter	Combined Tin Filter / Split Filter, and extra Tin Filter	Combined Tin Filter / Split Filter, and extra Tin Filter	Combined Tin Filter / Split Filter, and extra Tin Filter	Same as in the primary predicate devices
FAST 3D Camera	option for patient positioning with FAST 3D Camera installation option: ceiling mounted		option for patient positioning with FAST 3D Camera: installation option: ceiling mounted		Same as the primary predicate devices
High Power 70/ High Power 80	<u>Generator 90 kW:</u> up to 1100 mA (@70 kV) up to 1100 mA (@80 kV)	<u>Generator 105 kW:</u> up to 1200 mA (@70 kV) up to 1200 mA (@80 kV)	<u>Generator 90 kW:</u> up to 1100 mA (@70 kV) up to 1100 mA (@80 kV)	<u>Generator 105 kW:</u> up to 1200 mA (@70 kV) up to 1200 mA (@80 kV)	Same as the primary predicate devices

Hardware property	Subject device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM X.cite	**SOMATOM X.ceed**	**SOMATOM X.cite**	**SOMATOM X.ceed**	
	Generator 105 kW: up to 1200 mA (@70 kV) up to 1200 mA (@80 kV)	Generator 120 kW: up to 1300 mA (@70 kV) up to 1300 mA (@80 kV)	Generator 105 kW: up to 1200 mA (@70 kV) up to 1200 mA (@80 kV)	Generator 120 kW: up to 1300 mA (@70 kV) up to 1300 mA (@80 kV)	
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 2D camera	Patient observation camera integrated on gantry front		Patient observation camera integrated on gantry front		Same as the primary predicate devices
CARE Moodlight	LED lights integrated on the gantry front to indicate the system status: • System startup • Scan countdown • Radiation on		n.a.		CARE Moodlight is cleared in K233650 for the secondary predicate devices SOMATOM go. Platform CT scanner systems.
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 • Open interface compatible respiratory gating systems		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 devices, the subject devices SOMATOM X. Platform systems with software version *syngo* CT VB20 support acquisition of respiration-correlated scans. For measurement of the

Hardware property	Subject device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB20		Primary predicate device **SOMATOM X. Platform** with SOMARIS/10 *syngo* CT VB10 (K233650)		Assessment of the substantial equivalency (SE)
	SOMATOM X.cite	**SOMATOM X.ceed**	**SOMATOM X.cite**	**SOMATOM X.ceed**	
	• Open Online interface				breathing signal of the patient, interfaces for connecting of 3rd party respiratory gating devices are offered. Introduction of new Open Online interface. Open Online interface is cleared for the secondary predicate devices SOMATOM go. Platform with *syngo* CT VB20 in K250822.

Table 5: Comparison of software characteristics between the subject devices SOMATOM X. Platform CT scanner systems with software version syngo CT VB20 and the primary predicate devices with software version syngo CT VB10 (K233650).

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
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 VB10 Note: the short version *syngo* CT VB10 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	Software version upgraded due to new functionalities. Same as in the secondary predicate device

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
Workplace	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction System (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction System (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction System (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function	Same as the primary and secondary predicate devices
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	Same as the primary and secondary predicate devices
Detector firmware	Stellar detector firmware supported	Stellar detector firmware supported	Stellar detector firmware supported	Same as the primary and secondary predicate devices
Teamplay	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 that allow scanning with support of an external respiratory gating system	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocols that allow scanning with support of an external	Same as the primary and secondary predicate devices

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
	• 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) • Protocols supporting CT Intervention (scan modes: 2D i-sequence, 3D i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning • Protocols for DirectBreathhold	• 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) • Protocols supporting CT Intervention (scan modes: 2D i-sequence, 3D i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning • Protocols for DirectBreathhold	respiratory gating system • 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) • Protocols supporting CT Intervention (scan modes: 2D i-sequence, 3D i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning • Protocols for DirectBreathhold	
Advanced Reconstruction	Recon&GO: - Spectral Recon (Dual Energy Reconstruction including Virtual Unenhanced, Monoenergetic plus	Recon&GO: - Spectral Recon (Dual Energy Reconstruction including Virtual Unenhanced, Monoenergetic plus	Recon&GO: - Spectral Recon (Dual Energy Reconstruction including Virtual Unenhanced, Monoenergetic plus	Same as the primary and secondary predicate devices

Software property	Subject device **SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	Primary predicate device **SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	Secondary predicate device **SOMATOM go. Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	Assessment of the substantial equivalency (SE)
	- Inline Results DE SPP (Spectral Post-Processing with photon-counting image data) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	- Inline Results DE SPP (Spectral Post-Processing with photon-counting image data) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	- Inline Results DE SPP (Spectral Post-Processing with photon-counting image data) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	
Image viewing	CT View&GO offers: - basic post-processing viewer (CT View&GO) - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI) - Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	CT View&GO offers: - basic post-processing viewer (CT View&GO) - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI) - Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	CT View&GO offers: - basic post-processing viewer (CT View&GO) - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI) - Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	Same as the primary and secondary predicate devices
Software interface	• Recon&GO Inline Results Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k)	• 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	• Recon&GO Inline Results Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k)	Same as the secondary predicate devices In software version *syngo* CT VB20, the subject devices

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
	cleared as medical devices in their own right. • CT View&GO software interfaces (plug-ins and AV apps) for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone post-processing functionalities software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners • CT View&GO plug-in interface for myAblation Guide	devices in their own right. • CT View&GO software interfaces (plug-ins and AV apps) for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone post-processing functionalities software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners.	cleared as medical devices in their own right. • CT View&GO software interfaces (plug-ins and AV apps) for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone post-processing functionalities software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners • CT View&GO plug-in interface for myAblation Guide	introduce plug-in interface for the stand alone software application myAblation Guide.

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
Cybersecurity	IT Hardening	IT Hardening	IT Hardening	Same as the primary and secondary predicate devices
HD FoV	HD FoV 4.0 HD FoV 5.0	HD FoV 4.0	HD FoV 4.0 HD FoV 5.0	Same as the secondary predicate devices In addition to HD FoV 4.0, the subject devices SOMATOM X. Platform with *syngo* CT VB20 support a new generation of extended field of view reconstruction algorithm: HD FoV 5.0.
Standard technologies	FAST technologies CARE technologies GO technologies	FAST technologies CARE technologies GO technologies	FAST technologies CARE technologies GO technologies	Same as the primary and secondary predicate devices
Iterative Reconstruction Methods	ADMIRE iMAR	ADMIRE iMAR	ADMIRE iMAR SAFIRE	Same as the primary predicate devices
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)	Same as the primary and secondary predicate devices

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
DirectDensity	including relative electron density, relative mass density, and stopping power ratio	including relative electron density and relative mass density	including relative electron density, relative mass density, and stopping power ratio	Same as the secondary predicate devices Compared to the predicate devices, the subject devices SOMATOM X.cite and SOMATOM X.ceed with *syngo* CT VB20 support a modified DirectDensity functionality.
Stack artefact reduced reconstruction	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations ZeeFree RT: StackRecon types in respiratory-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: StackRecon types in respiratory-related examinations	Same as the secondary predicate devices ZeeFree RT is a new functionality introduced with *syngo* CT VB20 software version of the subject devices.
Oncology Exchange	transfer of prescription information from the ARIA Oncology Information System (OIS) to the CT scanner	n.a.	transfer of prescription information from the ARIA Oncology Information System (OIS) to the CT scanner	Same as the secondary predicate devices New functionality introduced with *syngo* CT VB20 software

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
				version of the subject devices.
DirectSetup Notes	patient and accessory setup documentation in the Scan&GO workflow	n.a.	patient and accessory setup documentation in the Scan&GO workflow	Same as the secondary predicate devices The subject devices SOMATOM X. Platform CT scanner systems are enabled to support DirectSetup Notes.
FAST Integrated Workflow (FAST 3D Camera)	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction • Collision Indication • Centerline/ Grid Overlay	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction • Collision Indication Centerline/ Grid Overlay	Same as the secondary predicate devices Compared to the predicate devices, the FAST 3D Camera of the subject devices supports in *syngo* CT VB20 a Collision indication and Centerline/Grid Overlay function.
FAST Planning	detects globally used scan and recon ranges from the topogram image additional body regions:	detects globally used scan and recon ranges from the topogram image	detects globally used scan and recon ranges from the topogram image additional body regions:	Same as the secondary predicate devices The subject devices SOMATOM X.

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
	- Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung - Extremities – Both knees		- Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung - Extremities – Both knees	Platform CT scanner systems with *syngo* VB20 support FAST Planning functionality with wide range of body regions. In *syngo* CT VB20, FAST Planning has been extended with additional body regions.
Eco Power Mode	reduce the energy consumption during idle times.	n.a.	reduce the energy consumption during idle times.	Same as the secondary predicate devices New feature introduced with *syngo* CT VB20 of the subject devices SOMATOM X.cite and SOMATOM X.ceed.
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	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	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	Same as the primary and the secondary predicate devices

Software property	Subject device	Primary predicate device	Secondary predicate device	Assessment of the substantial equivalency (SE)
	SOMATOM X.cite **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB20	**SOMATOM X.cite** **SOMATOM X.ceed** with SOMARIS/10 *syngo* CT VB10 (K233650)	**SOMATOM go.** **Platform** with SOMARIS/10 *syngo* CT VB20 (K250822)	
	external gating device.	external gating device.	external gating device.	
myExam Contrast	Bi-directional exchange of patient, scan, and injection parameters for a seamless synchronization of the CT scanner	n.a.	Bi-directional exchange of patient, scan, and injection parameters for a seamless synchronization of the CT scanner	Same as the secondary predicate devices New feature introduced with *syngo* CT VB20 of the subject devices SOMATOM X.cite and X.ceed.

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 X. Platform with *syngo* CT VB20 are comparable to the primary 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 X. Platform 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 6 below.

Table 6: 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. 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

Feature/Non-clinical supportive testing	Bench Testing performed
	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* • 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, the performance of the algorithm was evaluated by board-approved radio-oncologists by means of a retrospective blinded rater study on 30 patient cases of respiratory 4D CT examinations. The 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*

Feature/Non-clinical supportive testing	Bench Testing performed
	• 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 and general consensus standards considered for the subject devices is provided as Table 7 and Table 8 below.

Table 7: 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

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
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 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

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				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
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

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
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

In addition to the recognized consensus standards above, the general use standards NOT CURRENTLY RECOGNIZED by FDA, but considered for the subject devices are listed in Table 8.

Table 8: 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 basic safety and essential performance	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & 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 9 below.

Table 9: 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	08/11/2023
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	06/27/2025
Electromagnetic Compatibility (EMC) of Medical Devices	06/06/2022
Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices	09/06/2017
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 X. Platform 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 X.cite and SOMATOM X.ceed with software version *syngo* CT VB20 perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM X.cite and SOMATOM X.ceed 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.