September 3, 2024

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

Re: K241295
Trade/Device Name: SOMATOM On.site
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: July 31, 2024
Received: July 31, 2024

Dear Kenny 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 Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241295

Device Name

SOMATOM On.site

Indications for Use *(Describe)*

This computed tomography system is intended to generate and process cross-sectional images by computed reconstruction of x-ray transmission data within a 26 cm field-of-view, for the head and neck.

The images delivered by the system can be used by a trained staff as an aid in diagnosis.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
for K241295

SOMATOM On.site CT Scanner System

with software version SOMARIS/10 *syngo* CT VB10

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.
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Knoxville, TN 37932
Establishment Registration Number: 1034973

Importer/Distributor
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Malvern, PA 19355
Establishment Registration Number: 2240869

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

Note: Descriptions in this submission use the short company name Siemens. Brand name on all products is Siemens Healthineers.

Submitter Contact Person:
Kenny M Bello
Regulatory Affairs Professional
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Molecular Imaging
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Phone: (205) 856-6099
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II. Device Name and Classification

Product name:	SOMATOM On.site
Trade name:	SOMATOM On.site
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 On. CT scanner systems (with SOMARIS/10 *syngo* CT VA35 software)
510(k) Number:	K193277
Clearance Date:	July 22, 2020
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All predicate device recalls have been considered in the subject device design.

Secondary predicate device:

Trade Name:	SOMATOM go.Up (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.

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.

K193277 was a bundle submission with the following Siemens CT Scanner Systems: SOMATOM On.site and SOMATOM On.scene

IV. Device Description

Siemens intends to market a new software version, SOMARIS/10 *syngo* CT VB10 for the SOMATOM On. platform cleared in K193277 (clearance date July 22nd, 2020).

In software version *syngo* CT VA35 (K193277), the SOMATOM On. platform consists of two Computer Tomography (CT) scanner systems: SOMATOM On.scene for Mobile Stroke Units and SOMATOM On.site with an optional motorized base for in-hospital usage.

With the new software version SOMARIS/10 *syngo* CT VB10, the two SOMATOM On. scanners are rebranded as one scanner model only, SOMATOM On.site. The brand name SOMATOM On.scene is not used anymore.

The SOMATOM On.site with software version *syngo* CT VB10 is a mobile computed tomography (CT) scanner system that will be offered in two variants:

- SOMATOM On.site for Intensive Care Unit (ICU)
  Mobile CT scanner affixed to a motorized trolley for use in hospital situations. The scanner can be moved from patient bed to patient bed to perform scanning at the point of care. Although it might be used in other environments like emergency rooms or angiography labs, the main location where this scanner will be used, will be the intensive care unit (ICU).
- SOMATOM On.site for Mobile Stroke Unit (MSU)
  Mobile CT Scanner that is mounted to the floor of a diagnostic room or vehicle. The system main place where the scanner will be mounted is in a mobile stroke unit (MSU), which is a specific type of ambulance.

SOMATOM On.site

SOMARIS/10 syngo CT VB10

A: for Intensive Care Unit (ICU)

B: for Mobile Stroke Unit (MSU)

Figure 1: SOMATOM On.site with software version SOMARIS/10 syngo CT VB10 in two variants. ***A:*** *as a mobile CT scanner for Intensive Care Unit (ICU). The scanner is mounted on a trolley with wheels.* ***B:*** *as a mobile CT for Mobile Stroke Unit (MSU). The CT scanner is mounted in a vehicle.*

The subject device SOMATOM On.site with SOMARIS/10 *syngo* CT VB10 is a mobile Computed Tomography X-ray Systems which features a continuously rotating tube-detector system and function according to the fan beam principle. The SOMATOM On.site with software SOMARIS/10 *syngo* CT VB10 produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens Healthcare and other vendors as an aid in diagnosis and treatment preparation. The computer system integrated 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 On.site is *syngo* CT VB10 (SOMARIS/10 *syngo* CT VB10). It is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The software platform SOMARIS/10 *syngo* CT VB10 is designed to provide a plugin interface to integrate potential advanced post-processing tasks, tools, or extendable functionalities.

New software version *syngo* CT VB10 (SOMARIS/10 *syngo* CT VB10) is a modified software version based on *syngo* CT VA35 (SOMARIS/10 *syngo* CT VA35) which was cleared for the predicate device in K193277.

Software version SOMARIS/10 *syngo* CT VB10 will be offered ex-factory and as a mandatory exchange for the applicable existing SOMATOM On.site.

The subject device SOMATOM On.site will support previously cleared software and hardware features in addition to the applicable modifications as described within this submission. The intended use is same for subject and primary predicate device.

V. Indications for Use

This computed tomography system is intended to generate and process cross-sectional images by computed reconstruction of x-ray transmission data within a 26 cm field-of-view, for the head and neck.

The images delivered by the system can be used by a trained staff as an aid in diagnosis.

VI. Indications for Use Comparison

Subject Device Indications for Use:

This computed tomography system is intended to generate and process cross-sectional images by computed reconstruction of x-ray transmission data within a 26 cm field-of-view, for the head and neck.

The images delivered by the system can be used by a trained staff as an aid in diagnosis.

Primary Predicate Device Indications for Use:

This computed tomography system is intended to generate and process cross-sectional images by computed reconstruction of x-ray transmission data within a 25 cm field-of-view, primarily for the head and neck.

The images delivered by SOMATOM On.site and On.scene can be used by a trained physician as an aid in diagnosis.

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.

High risk populations are 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:

Compared to the primary predicate device:

In the sentence “This computed tomography system is intended to generate and process cross-sectional images by computed reconstruction of x-ray transmission data within a 25 cm field-of-view, for the head and neck.”:

- “25 cm field-of-view” is replaced with “26 cm field-of-view”. The field-of-view was inconsistently listed among the documents of the predicate device. However, 26 cm field-of-view is the correct field-of-view of the predicate device and the subject device.
- “primarily for the head and neck” is replaced with “for the head and neck”. In contrast to the predicate device, the subject device is only intended for head and neck scans.

In the sentence "The images delivered by SOMATOM On.site and On.scene can be used by a trained physician as an aid in diagnosis ":

- “trained physician” is replaced with “trained staff”. It can be assumed a trained physician is part of the trained staff.

To consider that in the US, the standard of care is for physicians to perform diagnosis/treatment, Siemens added the following statement in the 510(k) summary:

“*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.*”

- “SOMATOM On.site and SOMATOM On.scene” have been replaced with “system”, since with software version *syngo* CT VB10, the two SOMATOM On. scanners will be rebranded as one scanner model only.

Compared to the secondary predicate device:

- The subject device does not contain the phrase “treatment preparation and radiation therapy planning” in the sentence “The images delivered by the system can be used by a trained staff as an aid in diagnosis.” because SOMATOM On.site does not support intervention procedures and radiation therapy planning.
- SOMATOM On.site is not used in lung cancer screening. Therefore, the following part is not included in the indication for use statement of SOMATOM On.site.
  “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.”

VII. Comparison of Technological Characteristics with the Predicate Device

Supported by the subject device, SOMARIS/10 *syngo* CT VB10 software version is a further development of the SOMARIS/10 *syngo* CT VA35 software version which is cleared in K193277.

The SOMATOM On.site with SOMARIS/10 *syngo* CT VB10 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 SOMATOM On.site 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 VB10 software reuses all unmodified software features of the legacy software *syngo* CT VA35 cleared in K193277.

The intended use and fundamental scientific technology for the SOMATOM On.site remain unchanged from the predicate devices.

At a high level, the subject and predicate devices are based on the same subset of technological elements:

- System Acquisition – Continuously rotating tube detector system
- Iterative Reconstruction – Support of various iterative reconstruction principles
- A gantry translation system
- Stellar Detector technology
- Tin filtration technology
- Power Generator
- Remote Scan Control
- Standard CARE technologies
- Standard FAST technologies
- Standard GO technologies
- HD FoV

Compared to the predicate devices referenced in this submission, the subject device SOMATOM On.site with SOMARIS/10 *syngo* CT VB10 support the following modifications:

1) Modified hardware
2) Modified software
3) Modified accessories

4) Modified indications for use
5) Rebranding as one scanner model with two configurations, ICU and MSU

The configuration table and comparison table use the following terms to describe various technological characteristics in comparison to the primary and secondary predicate devices information:

Table 1: Overview of term definition

Term	Definition
Modified	The feature is modified from the predicate devices
Enabled	The feature is currently supported by other cleared Siemens CT systems. This feature will be supported for the subject device with software version SOMARIS/10 *syngo* CT VB10 and is unmodified from cleared version.
New	The feature is newly supported for Siemens CT Scanners and the subject device

1) Modified Hardware

Table 2: Overview of hardware modifications of SOMATOM On.site with software version SOMARIS/10 syngo CT VB10 compared to the predicate devices.

#	Hardware property	Subject device
		SOMATOM On.Site (ICU and MSU variants) with SOMARIS/10 *syngo* CT VB10
1.	CARE 2D Camera	**modified** (compared to the secondary predicate device SOMATOM go.Up)
2.	Tin Filter for Topogram	**enabled** (compared to the secondary predicate device SOMATOM go.Up)

2) Modified Software (*syngo* CT VB10)

Table 3: Overview of software modifications of SOMATOM On.site with software version SOMARIS/10 syngo CT VB10 compared to the predicate devices.

#	Software property	Subject device
		SOMATOM On.Site (ICU and MSU variants) with SOMARIS/10 *syngo* CT VB10
1.	Check&GO – Metal detection	**enabled**

#	Software property	Subject device
		SOMATOM On.Site (ICU and MSU variants) with SOMARIS/10 *syngo* CT VB10
		(compared to the secondary predicate device SOMATOM go.Up)
2.	myExam Companion – myExam Compass/myExam Cockpit	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
3.	Bolus Tracking	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
4.	Test Bolus	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
5.	ADMIRE	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
6.	FAST kV	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
7.	CARE Dose4D	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
8.	X-CARE	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
9.	FAST Planning	**enabled** (compared to the secondary predicate device SOMATOM go.Up)
10.	CT View&GO	**modified** (compared to the primary SOMATOM on.site and the secondary predicate device SOMATOM go.Up)
11.	Recon&GO	**modified** (compared to the primary SOMATOM on.site and the secondary predicate device SOMATOM go.Up)

A tabular summary of the comparable hardware and software properties between the subject device On.site with software version *syngo* CT VB10 and the predicate devices are listed in Table 4 and Table 5 below (modifications are in gray shaded sections).

Table 4: Comparison of hardware (HW) technological characteristics between the subject device SOMATOM On.site with software version syngo CT VB10 and the predicate devices.

Hardware (HW) property	**Subject device** **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	**Primary predicate device** **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	**Secondary predicate device** **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	**Assessment of the substantial equivalency (SE)**
Scanner	Head sized computed tomography scanner with continuously rotating tube and detector	Head sized computed tomography scanner with continuously rotating tube and detector	Whole body computed tomography scanner with continuously rotating tube and detector	**Same** as the primary predicate device
System configuration	Single source	Single source	Single source	**Same** as the primary and the secondary predicate device
Use environment	Radiology suite, Operating room (OR), Emergency Department/ Emergency room (ER/ED), clinic, patient rooms, exam rooms, mobile radiology vehicles, Intensive Care Unit (ICU), and Mobile Stroke Unit (MSU)	Radiology suite, Operating room (OR), Emergency Department/ Emergency room (ER/ED), clinic, patient rooms, exam rooms, mobile radiology vehicles, Intensive Care Unit (ICU), and Mobile Stroke Unit (MSU)	Professional Healthcare Facility	**Same** as the primary predicate device
X-ray tube	Stationary anode	Stationary anode	Rotary anode	**Same** as the primary predicate device
Tube technology	Monoblock: Integrates tube and generator to one component	Monoblock: Integrates tube and generator to one component	Chronon	**Same** as the primary predicate device

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
Tube current (mA)	1…25	3…25	13…400	Range of mA was extended at the lower end to increase flexibility for scans with lower mA and thus lower dose especially for topogram scans.
Tube voltage kV steps	80, 120	80, 120	80, 110, 130	**Same** as the primary predicate device
tube cooling	Liquid	Air and liquid	Liquid	**Same** as the secondary predicate device Focus on liquid cooling allows to get rid of air cooling and reduce the number of components in the system by reducing the air fan, which was needed.
Focal spot size (mm)	1.1 x 1.6	1.1 x 1.6	0.8 x 0.4 0.8 x 0.7	**Same** as the primary predicate device
Generator power max (kW)	3	3	32	**Same** as the primary predicate device

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
Detector material	Lightning UFC	Lightning UFC	Lightning UFC	**Same** as the primary and the secondary predicate device
Detector technology	Stellar based technology	Stellar based technology	Stellar based technology	**Same** as the primary and the secondary predicate device
Detector physical rows	32	32	32	**Same** as the primary and the secondary predicate device
Detector Z axis coverage (mm)	24	24	22.4	**Same** as the primary and the secondary predicate device
Detector slice width (mm)	0.75	0.75	0.7	**Same** as the primary predicate device
Detector DAS channel No./row	416	416	768	**Same** as the primary predicate device
Detector Max. number of slices	Acquired: 32 Reconstructed: 32	Acquired: 32 Reconstructed: 32	Acquired: 32 Reconstructed: 64	**Same** as the primary predicate device
Translation/table	Translation on fixed base	Translation on fixed base	Translating patient table	**Same** as the primary predicate device
Max. scan range (cm)	25	25	160 or 200 depending on the patient table used	**Same** as primary predicate device

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
Gantry scan FoV (cm)	26	26	50	**Same** as the primary predicate device
Gantry rotation time (sec)	1.0	1.0	0,8, 1.0, 1.5	**Same** as the primary predicate device
Gantry bore diameter (cm)	35	35	70	**Same** as the primary predicate device
Gantry tilt (degrees)	No tilt	No tilt	Yes (+/-25°)	**Same** as the primary predicate device
Selectable filtration	Tin Filter/Tin Filtration technology	N.A.	Tin Filter/Tin Filtration technology	**Same** as the secondary predicate device Tin filtration allows to lower the dose on topogram scans.
Recon speed (images/sec)	20 for FBP	13 for FBP	• 30 fps for FBP • 75 fps for FBP (depending on the IRS)	Recon speed increased due to new hardware (image reconstruction system) with increased performance
Spiral scan	yes	yes	yes	**Same** as the primary predicate device

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
System Configuration	Single source	Single source	Single source	**Same** as the primary predicate device
Patient support	Patient support mounts directly to the scanner and is pre-aligned to alleviate imaging artifacts or loss of quality	Patient support mounts directly to the scanner and is pre-aligned to alleviate imaging artifacts or loss of quality	Patient support is part of patient table which is mounted to scanner and is pre-aligned laterally; requires operator to align vertically to center patient to alleviate imaging artifacts or loss of quality	**Same** as the primary predicate device
Radiation shielding	Yes Gantry shielded internally with lead Externally contain lead lined full-length drapes to entirely contain the scattered radiation from all angles Operator can stand at side of machine. Wearing of protective shielding is optional.	Yes Gantry shielded internally with lead Externally contain lead lined full-length drapes to entirely contain the scattered radiation from all angles Operator can stand at side of machine. Wearing of protective shielding is optional.	No requires to be installed in a shielded room with door light and interlock	**Same** as the primary predicate device
CARE 2D Camera	integrated into the gantry front to observe the patient during examination	N/A	integrated into the gantry front and back to observe the patient during examination	**Equivalent** In software version *syngo* CT VB10, a 2D

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
				Camera hardware is integrated into the gantry front. This allows to observe the patient from the front of the system when the front radiation shield was closed. The bore light illuminates the bore so the patient's face can be seen on the 2D Camera images.
Scanner Mobility				
Mobile/ Fixed	Mobile/ fixed • SOMATOM On.site for Intensive Care Unit (ICU): Mobile CT scanner affixed to an optional motorized trolley for use in hospital trauma situations. • SOMATOM On.site for Mobile Stroke Unit (MSU): Fixed CT Scanner that can be mounted to the floor of a	Mobile/ fixed • SOMATOM On.site: Mobile CT scanner affixed to an optional motorized trolley for use in hospital trauma situations. • SOMATOM On.scene: Fixed CT Scanner that can be mounted to the floor of a diagnostic room or vehicle, e.g. Mobile Stroke Unit (MSU)	fixed	**Same** as the primary predicate device Note: Rebranding of the CT system as SOMATOM On.site only with two variants, ICU and MSU; mobile/fixed method is unchanged compared

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
	diagnostic room or vehicle, e.g. Mobile Stroke Unit (MSU)			to the primary predicate device.
Mobile method	2 independent motorized rear wheels with 2 front caster wheels	2 independent motorized rear wheels with 2 front caster wheels	N/A	**Same** as the primary predicate device
Mobile speed	2.8 mph max	2.5 mph max	N/A	**Equivalent** Slightly increased by 0.3 mph mobile speed to meet customers' satisfaction
Break	yes	yes	N/A	**Same** as the primary predicate device
Drive handle	Yes (ICU variant)	Yes (ICU variant)	N/A	**Same** as the primary predicate device
Integrated Drive camera	Yes (ICU variant)	Yes (ICU variant)	N/A	**Same** as the primary predicate device
Scanner power				
External power	100 – 240 Vac 50/60 Hz 0.825 kW	100 – 240 Vac 50/60 Hz 1.2 kW	200 – 400 VAC 50/60 Hz 50 kW	**Equivalent** Reduced external power consumption due to new battery technology

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
Internal power storage	1 x 48 V Lithium-ion battery	4 x 12 V sealed lead-acid battery	No	Change of technology from lead-acid batteries to Lithium-ion batteries in order to increase battery capacity and lifetime.
Electrical safety	Circuit breakers and isolation transformer	Circuit breakers and isolation transformer	Circuit breakers	**Same** as the primary predicate device
EMERGENCY-stop key	yes	yes	yes	**Same** as the primary predicate device
Operator Interface				
Operator Control Interface on Scanner	Integrated touch monitor + button panel	integrated touch screen tablet PC +physical keyboard+ button panel	Removable touch screen + button panel	Changed from tablet to touch monitor & desktop PC setup. Increased performance of desktop PC, bigger and tiltable screen.
Remote control	Wired remote control for service	Optional wired	Wired/ wireless	**Same** as the primary predicate device
Workstation	No, access through integrated touch monitor	No, access through tablet PC	*syngo* Acquisition Workplace	**Equivalent** to the primary device The display in the subject device is a

Hardware (HW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
				touch monitor while in the primary predicate device the display was a tablet PC. The interface provides a similar user experience, while the performance of the backend PC could be increased.
Keyboard/mouse	Virtual keyboard and touch interaction on integrated touch monitor	included	included	**Equivalent** In the subjective device keyboard and mouse interactions are all performed with a virtual keyboard and touch interactions on the screen.

Table 5: Comparison of software (SW) technological characteristics between the subject device SOMATOM On.site with software version syngo CT VB10 and the predicate devices.

Software (SW) property	**Subject device** **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	**Primary predicate device** **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	**Secondary predicate device** **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	**Assessment of the substantial equivalency (SE)**
Operating System	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 VA35 Note: the short version *syngo* CT VA35 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	New software version
Workplace	• *syngo* Acquisition Workplace – Touch UI works as integrated Image Computing System (ICS) to enable all-in-one concept for mobile CT • Image reconstruction System (IRS)	• *syngo* Acquisition Workplace – Touch UI works as integrated Image Computing System (ICS) to enable all-in-one concept for mobile CT • Image reconstruction System (IRS)	*syngo* Acquisition Workplace named as “myExam Console” – Gantry-integrated ICS • Image reconstruction System (IRS) • 2nd Acquisition Workplace named as “myExam Satellite”	**Same** as the primary predicate device
Standard system software	• *syngo* Examination • *syngo* Viewing • *syngo* Filming	• *syngo Examination* • *syngo Viewing* • *syngo Filming*	• *syngo Examination* • *syngo Viewing* • *syngo Filming*	**Same** as the primary predicate device

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
	• *syngo* Archiving & Networking	• *syngo Archiving & Networking*	• *syngo Archiving & Networking*	
Detector firmware	Stellar detector firmware supported	Stellar detector firmware supported	Stellar detector firmware supported	**Same** as the primary and the secondary predicate device
Protocols	• Examination Protocols for Head and Neck • Protocol supporting contrast bolus-triggered data acquisition • Adult/ pediatric protocols for head and neck examination • Protocol overwrite protection • Administrator privileges for protocol creation	• Examination Protocols for Head and Neck • Protocol supporting contrast bolus-triggered data acquisition • Adult/ pediatric protocols for head and neck examination • Protocol overwrite protection • Administrator privileges for protocol creation	• Protocols for Radiation Therapy Planning support patient marking • Protocols that allow scanning with support of an external respiratory gating system (ANZAI, Varian RGSC) • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Adult protocols • Pediatric protocols • Flex Dose Profile • Dual Energy acquisition (TwinBeam DE and TwinSpiral DE) • Dynamic imaging (Flex 4D Spiral)	**Same** as the primary predicate device

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
			• Protocols supporting Intervention (scan modes: i-sequence, i-spiral, i-Fluoro) • Protocol overwrite protection • Administrator privileges for protocol creation • Protocols for DirectBreathhold • Protocols supporting Cardiac Scanning	
Touch UI – user modes	Touch screen display with two modes: • Basic User mode (Touch UI) Routine examination workflow, e.g. plan, control, and acquire diagnostic scans. • Advanced mode (Advanced UI) Contains more advanced functionalities, such as quality assurance, as well as administration and configuration tasks.	Touch screen display with two modes: • Basic User Mode (Scan&GO) Routine examination workflow, e.g. plan, control, and acquire diagnostic scans. • Advanced mode (Advanced UI) Contains more advanced functionalities, such as quality assurance, as well as administration and configuration tasks.	Touch screen display on Scan&GO mobile tablet: provides mainly supportive functions required for planning and controlling scans; not intended to be used for image acquiring, image storage and image reconstruction.	**Same** user modes as the primary predicate device

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
	Connecting or removing scan ranges Modifying parameters	Connecting or removing scan ranges Modifying parameters		
Advanced Reconstruction	Recon&GO: • Inline Anatomical ranges (Parallel/Radial) • Inline table and bone removal	Recon&GO: no integrated advanced visualization tools	Recon&GO: • Spectral Recon • Inline Results DE SPP • Inline Anatomical ranges (Parallel/Radial) • Inline Spine and Rib Ranges • Inline table and bone removal	Compared to the primary predicate device, a subset of advanced visualization tools (Recon&GO - Inline results) is now integrated within the Recon&GO of the subject device SOMATOM On.site with *syngo* CT VB10. Same as the secondary predicate device the visualization tools Inline Anatomical ranges (Parallel/Radial) and Inline table and bone removal are now integrated within

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
				Recon&GO of the subject device.
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 • Basic manipulation tools: ROI HU Threshold, Automated table and bone removal	CT View&GO offers: • basic post-processing viewer (CT View&GO) • 2D and 3D (MPR, VRT, MIP and minIP) • Evaluation tools, Filming, Printing	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 Threshold, Average, Automated Bone and Table removal	Compared to the primary predicate device, the CT View&GO function of the subject device SOMATOM On.site with *syngo* CT VB10 supports more visualization and manipulation tools. Same as the secondary predicate device ROI HU Threshold and Automated Table and Bone removal are now integrated in the subject device SOMATOM On.site with *syngo* CT VB10

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
Post-Processing 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. • 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 the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed	• 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. • 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 the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed	• 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. • 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 the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed	**Same** as the primary and the secondary predicate device.

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
	by Computed Tomography scanners.	by Computed Tomography scanners.	by Computed Tomography scanners.	
Check&GO	Check&GO Quality check of the images before sending them to the reading workplace, e.g. PACS Check&GO – Metal detection detects metal objects on or near the patient, including objects required for the examination, for example, ECG wires.	Check&GO Quality check of the images before sending them to the reading workplace, e.g. PACS	Check&GO Quality check of the images before sending them to the reading workplace, e.g. PACS Check&GO – Metal detection detects metal objects on or near the patient, including objects required for the examination, for example, ECG wires.	**Same** as the secondary predicate device
myExam Companion – myExam Compass/myExam Cockpit	• myExam Compass collects information about the current patient to dynamically adapt the scan parameters or exchange recon jobs according to the patient's characteristics • myExam Cockpit option of displaying, modifying, creating, and deleting Clinical Decision Trees (CDTs). myExam Compass functionality offers the possibility to activate/deactivate diagnostic	N/A	• myExam Compass collects information about the current patient to dynamically adapt the scan parameters or exchange recon jobs according to the patient's characteristics • myExam Cockpit option of displaying, modifying, creating, and deleting Clinical Decision Trees (CDTs). myExam Compass functionality offers the possibility to activate/deactivate diagnostic	**Same** as the secondary predicate device

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
	scan ranges, Bolus Tracking and Test Bolus ranges. myExam Cockpit allows to define these new settings.		scan ranges, Bolus Tracking and Test Bolus ranges. myExam Cockpit allows to define these new settings.	
Cybersecurity	IT security functionalities supported	IT security functionalities supported	IT security functionalities supported (IT Hardening)	**Same** as the primary predicate device
Teamplay	Support of teamplay protocols	Support of teamplay protocols	Support of teamplay protocols	**Same** as the primary and the secondary predicate device
HD FoV	supported	supported	supported	**Same** as the primary predicate device
Standard Technologies	FAST Features CARE Features GO technology	FAST Features GO technology	FAST Features CARE Features GO technology	**Same** as the secondary predicate device
Dose modulation	FAST kV CARE Dose 4D X-CARE Topogram with Tin Filter Technology	N/A	FAST kV CARE Dose 4D X-CARE Topogram with Tin Filter Technology	**Same** as the secondary predicate device
FAST Planning	Selects the body region on the topogram image that is to be detected for the recon range	N/A	Selects the body region on the topogram image that is to be detected for the recon range	**Same** as the secondary predicate device

Software (SW) property	Subject device **SOMATOM On.site** SOMARIS/10 *syngo* CT VB10	Primary predicate device **SOMATOM On. Scanners** SOMARIS/10 *syngo* CT VA35 (K193277)	Secondary predicate device **SOMATOM go.Up** SOMARIS/10 *syngo* CT VB10 (K233650)	Assessment of the substantial equivalency (SE)
Iterative Reconstruction Methods	iMAR ADMIRE	iMAR SAFIRE	iMAR SAFIRE	With software version VB10, SAFIRE is descoped and replaced by ADMIRE, because of improved algorithm performance. ADMIRE was originally approved with K133646 and it is the same as the SOMATOM go. Platform with SOMARIS/10 *syngo* CT VB10 (K233650). K233650 is a bundle 510(k) with various Siemens CT scanner systems including SOMATOM go.Up.

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 device SOMATOM On.site with *syngo* CT VB10 is comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

VIII. Performance Data

Non-Clinical Testing

Non-clinical testing, (integration and functional) including phantom tests were conducted for the SOMATOM On.site 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.

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 kV	The bench test evaluates the performance of FAST kV. The objective of the test is to demonstrate: - That image quality (in terms of contrast-to-noise ratio) at the different kV settings offered by the system is consistent when using FAST kV. - That radiation dose levels are reduced at 80 kV. The test results show: - For iodine and calcium contrast material inserts in a cylindrical 20 cm water phantom with corresponding FAST kV settings

Feature/Non-clinical supportive testing	Bench Testing performed
	'vascular' and 'bone/calcium', CNR values at 80 kV and 120 kV are consistent (deviations well below 15%). In comparison to 120 kV, dose levels at 80 kV are slightly reduced (-5%) with the 'bone/calcium' setting and are substantially reduced (-44%) with the 'vascular' setting of FAST kV.
CARE Dose4D	The bench test evaluates the performance of CARE Dose4D in the subject device SOMATOM On.site as compared to the predicate device SOMATOM go.Up. The objective of the bench test is to demonstrate: - comparable performance of CARE Dose4D in SOMATOM On.site and the predicate device SOMATOM go.Up. - CARE Dose4D leads to reduced dose levels at consistent image quality. Phantom-based measurements have been performed on the subject device SOMATOM On.site (intended for head and neck scans) and the predicate device SOMATOM go.Up (whole body diagnostic scanner). The performance of CARE Dose4D is assessed with respect to radiation dose ($CTDI_{vol}$) and image noise levels (image quality). The evaluation showed equivalent performance results for CARE Dose4D in the subject device SOMATOM On.site and the predicate device SOMATOM go.Up. It can be concluded the performance of the CARE Dose4D functionalities is comparable to those of the predicate device SOMATOM go.Up. Consequently, the results and the conclusions of the clinical publications listed in the bench testing are transferable also for the subject device SOMATOM On.site. CARE Dose4D is a well-established tube current modulation (TCM) technology, which is offered on Siemens and Siemens Healthineers CT systems since the early 2000s. The bench test document lists various clinical publications that show the dose reduction potential of TCM in general and specifically of CARE Dose4D.
X-CARE	The bench test evaluates the performance of X-CARE in the subject device SOMATOM On.site as compared to the predicate device SOMATOM go.Up. The objective of the bench test is to demonstrate: - comparable performance of X-CARE in SOMATOM On.site and the predicate device SOMATOM go.Up. - X-CARE leads to reduced dose levels to the eye lenses at consistent image quality. Phantom-based measurements have been performed on the subject device SOMATOM On.site (intended for head and neck scans) and the

Feature/Non-clinical supportive testing	Bench Testing performed
	predicate device SOMATOM go.Up (whole body diagnostic scanner). The performance of X-CARE is assessed with respect to radiation dose ($CTDI_{vol}$) and image noise levels (image quality). The evaluation showed equivalent performance results for X-CARE in the subject device SOMATOM On.site and the predicate device SOMATOM go.Up. It can be concluded the performance of the X-CARE functionality is comparable to those of the predicate device SOMATOM go.Up. Consequently, the results and the conclusions of the clinical publications listed in the bench testing are transferable also for the subject device SOMATOM On.site. X-CARE is a well-established, organ-based tube current modulation technology, which is offered on Siemens and Siemens Healthineers CT systems since the early 2010s. The bench test document lists various clinical publications that show the organ dose reduction potential of X-CARE.
ADMIRE	The bench test evaluates the characteristics of the iterative reconstruction algorithm ADMIRE on the On.site. The objectives of this test are to demonstrate that ADMIRE reduces image noise at the Somatom On.site CT scanner and maintains a natural image impression without noticeable loss of sharpness. The mean CT values, and specifically the water value, do not vary when ADMIRE reconstruction is used instead of a weighted filtered back-projection WFBP. The test results show: • The water value and the CT value of the PTFE object remain constant with increasing ADMIRE strength settings and compared to the WFBP reconstruction. • The sharpness, demonstrated with an edge MTF function of the PTFE object, is constant with increasing ADMIRE strength setting and compared to the WFBP reconstruction. • The image noise decreases compared to the WFBP setting and with increasing ADMIRE strength. Image impression is maintained as the shape of the noise distribution remains Gaussian with any ADMIRE strength setting.

A list of recognized and general consensus standards considered for the subject device 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
12/19/2022	12-349	NEMA	PS 3.1 - 3.20 2022d	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
07/07/2021	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-

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

Standard Developing Organization	Standard Designation Number and Date	Title of Standard	How was Standard Used
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	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
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.

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 device SOMATOM On.site performs as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM On.site 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 device is as safe, as effective, and performs as well as or better than the predicate devices.