February 12, 2025

Siemens Medical Solutions USA, Inc.
℅ Tabitha Estes
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE, TN 37932

Re: K243523
Trade/Device Name: NAEOTOM Alpha.Peak/ NAEOTOM Alpha; NAEOTOM Alpha.Pro; NAEOTOM Alpha.Prime
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: November 14, 2024
Received: November 14, 2024

Dear Tabitha Estes:

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)*

K243523

Device Name

NAEOTOM Alpha.Peak/ NAEOTOM Alpha;
NAEOTOM Alpha.Pro;
NAEOTOM Alpha.Prime

Indications for Use *(Describe)*

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.
The images delivered by the system can be used by a trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.
This CT system can be used for low dose lung cancer screening in high risk populations*.
* As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K243523

510(k) Summary
for
NAEOTOM 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. 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
Siemens Healthineers AG
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:
Tabitha Estes
Regulatory Affairs
Siemens Medical Solutions USA, Inc.
(865) 804-4553 (work cell)
tabitha.estes@Siemens-healthineers.com

II. Device Name and Classification

Product name	Trade name
NAEOTOM Alpha	NAEOTOM Alpha.Peak NAEOTOM Alpha
NAEOTOM Alpha.Pro	NAEOTOM Alpha.Pro
NAEOTOM Alpha.Prime	NAEOTOM Alpha.Prime

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:	NAEOTOM Alpha
510(k) Number:	K233657
Clearance Date:	March 28, 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 X.ceed
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.

Reference Predicate Device:

Trade Name:	SOMATOM go. Platform
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 510(k) including the SOMATOM go. Platform (SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim and SOMATOM go.Open Pro) and the SOMATOM X. Platform (SOMATOM X.cite and SOMATOM X.ceed).

IV. Device Description

Siemens intends to market a new Single source CT system NAEOTOM Alpha.Prime and a new Dual Source CT system NAEOTOM Alpha.Pro based on the SOMARIS/10 software platform.

Siemens also intends to market updated software version, SOMARIS/10 *syngo* CT VB20, for the new NAEOTOM CT scanner systems and for the NAEOTOM Alpha cleared in K233657 (clearance date March 28th, 2024). The updated software version SOMARIS/10 *syngo* CT VB20 incorporates mainly features for radiotherapy planning support.

With the new software version SOMARIS/10 *syngo* CT VB20, the trade name of NAEOTOM Alpha cleared in K233657 has been changed to NAEOTOM Alpha.Peak for ex-factory systems. Systems already installed will receive the software update without change of the trade name. The system label keeps the product name NAEOTOM Alpha. System label information and UDI are not changed and remain the same as the original submitted.

For simplicity, the product name of NAEOTOM Alpha will be used throughout this submission instead of the trade name NAEOTOM Alpha.Peak.

The subject devices NAEOTOM Alpha (trade name ex-factory CT systems: NAEOTOM Alpha.Peak) and NAEOTOM Alpha.Pro with software version SOMARIS/10 *syngo* CT VB20 are Computed Tomography X-ray systems which feature two continuously rotating tube-detector systems, denominated as A- and B-systems respectively (dual source NAEOTOM CT scanner system).

The subject device NAEOTOM Alpha.Prime with software version SOMARIS/10 *syngo* CT VB20 is a Computed Tomography X-ray system which features one continuously rotating tube-detector systems, denominated as A-system (single source NAEOTOM Alpha CT scanner system).

The detectors' function is based on photon-counting technology.

In this submission, the above-mentioned CT scanner systems are jointly referred to as subject devices by "NAEOTOM CT scanner systems".

The NAEOTOM CT scanner systems with SOMARIS/10 syngo CT VB20 produce CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens and other vendors. The CT images 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. The radiation therapy planning support includes, 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 the NAEOTOM CT scanner systems is *syngo* CT VB20 (SOMARIS/10 *syngo* CT VB20). 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 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.

Software version *syngo* CT VB20 (SOMARIS/10 *syngo* CT VB20) is a modified software version of the primary predicate device NAEOTOM Alpha, *syngo* CT VB10 (SOMARIS/10 *syngo* CT VB10) cleared in K233657.

Software version SOMARIS/10 *syngo* CT VB20 will be offered ex-factory and as optional upgrade for the existing NAEOTOM Alpha systems.

The bundle approach is feasible for this submission since the subject devices have similar technological characteristics, software operating platform, and supported software characteristics. 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 and treatment 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 secondary predicate device Indications for Use (K233650).

Compared to the primary predicate device, the indications for Use of the subject devices have been extended with the phrase “radiation therapy planning” in the sentence “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.”. The extension of the indications for use reflects the support for radiotherapy planning introduced with the software version *syngo* CT VB20 of the subject devices.

None of the intended uses include computed tomography as the principal means of guidance in invasive procedures (involving the introduction of a device, such as a needle or a catheter into the body of the patient).

The subject devices NAEOTOM CT scanner systems are not the principal means of guidance, because the CT Systems do not guide the invasive procedures, the needle orientation and the needle advance and handling are always done under the physician's control.

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 K233657.

The subject devices NAEOTOM CT scanner systems 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 NAEOTOM CT scanner systems 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 K233657. 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 NAEOTOM Alpha 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
- QuantaMax Detector
- 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 Guide)
- Optional support of FAST 3D Camera operation for fast patient positioning workflow
- Scanner display and control functionality
- Remote Scan Control
- Long scan range

The subject devices NAEOTOM 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 the Table 2. 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 2 indicate the clearance of the technological properties in the corresponding predicate device.

The modification overview in Table 2 uses the terms "new, modified, or enabled" to describe various technological characteristics of the subject devices in comparison to the primary and secondary predicate devices. The definition of the above-mentioned terms is provided in the following Table 1.

Table 1: Overview of term definition.

Term	Definition
New	The feature is newly supported for Siemens CT scanners and the subject device
Modified	This feature is a modified form of a feature cleared within the primary and/or secondary 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 primary/secondary predicate device.
n.a.	The feature is not supported by the subject device or by the primary and/or secondary predicate device.

The following Table 2 provides a modification overview of the subject devices at a high-level.

Table 2: High-level overview of key hardware (HW) and software (SW) modifications of the Dual source subject devices NAEOTOM Alpha (trade name ex-factory: NAEOTOM Alpha.Peak; trade name installed base: NAEOTOM Alpha) and

NAEOTOM Alpha.Pro and the Single source subject device NAEOTOM Alpha.Prime with software version SOMARIS/10 syngo CT VB20 compared to the predicate devices.

	Technological property	**HW/ SW change**	**Subject devices**			**Predicate devices**	
			Dual Source		Single source	Dual Source	Single source
			NAEOTOM Alpha *syngo* CT VB20	**NAEOTOM Alpha.Pro** *syngo* CT VB20	**NAEOTOM Alpha.Prime** *syngo* CT VB20	**NAEOTOM Alpha** *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** *syngo* CT VB10 (K233650)
1.	Respiratory Motion Management - *Interfaces for respiratory gating:* - Varian RGSC - Anzai - Open Interface - Open Online Interface	HW	**modified**[1]	**modified**[1]	**modified**[1]	n.a.	cleared
2.	Respiratory Motion Management - *FAST 4D*	SW	**enabled**	**enabled**	**enabled**	n.a.	cleared
3.	Respiratory Motion Management – *Direct i4D*	SW	**enabled**	**enabled**	**enabled**	n.a.	cleared
4.	Respiratory Motion Management - *DirectBreathhold*	SW	**enabled**	**enabled**	**enabled**	n.a.	cleared
5.	CT View&GO - Sim&GO	SW	**modified**[2]	**modified**[2]	**modified**[2]	cleared	cleared
6.	Direct Laser Steering	HW/ SW	**enabled**	**enabled**	**enabled**	n.a.	cleared
7.	Recon&GO	SW	**modified**[2]	**modified**[2]	**modified**[2]	cleared	cleared

[1] The listed interfaces for respiratory gating are implemented unchanged in the subject devices compared to the secondary predicate device SOMATOM X.ceed with exception of Open Online Interface. Open Online Interface is not available on the predicate devices and the interface is new for this submission.

[2] In the subject devices NAEOTOM Alpha, NAEOTOM Alpha.Pro, and NAEOTOM Alpha.Prime with *syngo* CT VB20, the functionalities Recon&GO Inline Results and CT View&GO support the same functions as cleared in the secondary predicate device SOMATOM X.ceed but are modified compared to the primary predicate device NAEOTOM Alpha with software version *syngo* CT VB10.

	Technological property	HW/ SW change	Subject devices			Predicate devices	
			Dual Source		Single source	Dual Source	Single source
			NAEOTOM Alpha *syngo* CT VB20	**NAEOTOM Alpha.Pro** *syngo* CT VB20	**NAEOTOM Alpha.Prime** *syngo* CT VB20	**NAEOTOM Alpha** *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** *syngo* CT VB10 (K233650)
	- RT planning						
8.	Oncology Exchange	SW	**new**	**new**	**new**	n.a.	n.a.
9.	DirectSetupNotes	SW	**enabled**[3]	**enabled**[3]	**enabled**[3]	n.a.	cleared
10.	FAST 3D Camera/ FAST Integrated Workflow	SW/ HW	**modified**[4]	**modified**[4]	**modified**[4]	cleared	cleared
11.	Flex 4D Spiral	SW	**modified**[4]	**modified**[4]	**modified**[4]	cleared	cleared
12.	FAST Planning	SW	**modified**[4]	**modified**[4]	**modified**[4]	cleared	cleared
13.	CARE Moodlight	HW	**enabled**[5]	**enabled**[5]	**enabled**[5]	n.a.	n.a.
14.	Eco Power Mode	HW/ SW	**new**	**new**	**new**	n.a.	n.a.
15.	Power Shaver	SW/ HW	**n.a.**	**n.a.**	**new**	n.a.	n.a.
16.	myExam Companion – myExam Compass/ myExam Cockpit	SW	**modified**[4]	**modified**[4]	**modified**[4]	cleared	cleared

A tabular summary of the comparable hardware and software properties between the subject devices NAEOTOM CT scanner systems with software version *syngo* CT VB20 and the

[3] DirectSetupNotes is cleared in K233650 for the SOMATOM go.Sim and SOMATOM go.Open Pro. K233650 is a bundle 510(k) including the SOMATOM go. Platform (SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim and SOMATOM go.Open Pro) and the SOMATOM X. Platform (SOMATOM X.cite and SOMATOM X.ceed).

[4] These features are modified compared to the same feature cleared in the primary and secondary predicate device.

[5] CARE Moodlight is cleared in K233650 for the SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.Top and SOMATOM go.All. K233650 is a bundle 510(k) including the SOMATOM go. Platform (SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim and SOMATOM go.Open Pro) and the SOMATOM X. Platform (SOMATOM X.cite and SOMATOM X.ceed).

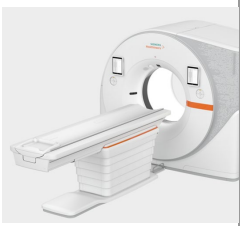
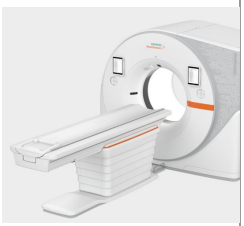
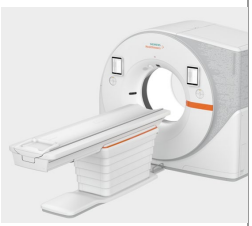
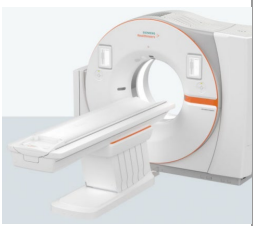
primary/secondary predicate devices are listed in the following tables (modifications are in gray shaded sections).

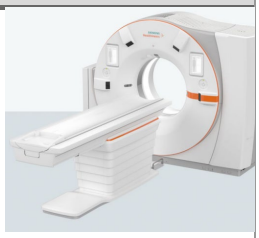
Table 3 compares the hardware properties of the dual source subject devices NAEOTOM Alpha (trade name ex-factory: NAEOTOM Alpha.Peak; trade name installed base: NAEOTOM Alpha) and NAEOTOM Alpha.Pro with the primary/secondary predicate devices.

Table 4 provides a comparison of the hardware properties between the single source subject device NAEOTOM Alpha.Prime and the primary/secondary predicate devices.

Table 5 compares the software technological characteristics of the subject devices and the predicate devices.

Table 3: Hardware characteristics for the dual source subject devices NAEOTOM Alpha (trade name ex-factory: NAEOTOM Alpha.Peak; trade name installed base: NAEOTOM Alpha) and NAEOTOM Alpha.Pro with software version SOMARIS/10 syngo CT VB20 compared to the predicate devices.

Hardware property	**Subject device** (Dual source NAEOTOM CT systems)		**Primary predicate device**	**Secondary predicate device**
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Scanner	whole body X-ray computed tomography (CT) scanner	whole body X-ray computed tomography (CT) scanner	whole body X-ray computed tomography (CT) scanner	whole body X-ray computed tomography (CT) scanner
Product name	NAEOTOM Alpha	NAEOTOM Alpha.Pro	NAEOTOM Alpha	SOMATOM X.ceed
Trade name	• Ex-factory CT systems: NAEOTOM Alpha.Peak • Installed base CT systems: NAEOTOM Alpha	• Ex-factory CT systems: NAEOTOM Alpha.Pro • Installed base CT systems: n.a., new CT system	NAEOTOM Alpha	SOMATOM X.ceed
Design	without myNeedle Laser: 	without myNeedle Laser: 	without myNeedle Laser: 	without myNeedle Laser:  with myNeedle Laser:

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
	with myNeedle Laser: 	with myNeedle Laser: 	with myNeedle Laser: 	
System configuration	Dual Source	Dual Source	Dual Source	Single Source
Environment of Use	Professional Healthcare Facility	Professional Healthcare Facility	Professional Healthcare Facility	Professional Healthcare Facility
Generator max. power (kW)	2x 120	2x 120	2x 120	105 or 120
Detector technology	QuantaMax direct conversion with “Quantum Technology”	QuantaMax direct conversion with “Quantum Technology”	QuantaMax direct conversion with “Quantum Technology”	Stellar^{Infinity} UFC (Ultra Fast Ceramic)
Detector volume coverage (mm)	2x 57.6	2x 38.4	2x 57.6	38.4
Detector physical rows	2x 288	2x 192	2x 288	64
Detector slice width (mm)	0.2	0.2	0.2	0.6
Detector DAS channel no.	2752 (A system) 1984 (B system)	2752 (A system) 1984 (B system)	2752 (A system) 1984 (B system)	920
Tube	VECTRON	VECTRON	VECTRON	VECTRON

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
technology				
Tube kV steps	70, 90, 100, 120, 140, 150 (150 kV only available on the smaller tube-detector system (B system) and only in combination with the additional Sn filter, 0.7 mm)	70, 90, 100, 120, 140, 150 (150 kV only available on the smaller tube-detector system (B system) and only in combination with the additional Sn filter, 0.7 mm)	70, 90, 100, 120, 140, 150 (150 kV only available on the smaller tube-detector system (B system) and only in combination with the additional Sn filter, 0.7 mm)	70, 80, 90, 100, 110, 120, 130, 140, 150
Tube max. current (mA)	2x 1300	2x 1300	2x 1300	1200 mA (for 105 kW) 1300 mA (for 120 kW)
Tube tube focus (mm)	0.4 x 0.5/8° 0.6 x 0.7/8° 0.8 x 1.1/8° (for both tubes)	0.4 x 0.5/8° 0.6 x 0.7/8° 0.8 x 1.1/8° (for both tubes)	0.4 x 0.5/8° 0.6 x 0.7/8° 0.8 x 1.1/8° (for both tubes)	0.4 x 0.5/8° 0.6 x 0.7/8° 0.8 x 1.1/8°
Tube heat storage capacity (MHU)	higher than 30	higher than 30	higher than 30	higher than 30
Tube cooling rate (MHU/min)	2.7	2.7	2.7	2.7
Gantry bore size (cm)	82	82	82	82
Gantry Scan FoV (cm)	50	50	50	50
Gantry	81.5	81.5	81.5	81.5

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Extended FoV (cm)				
Gantry rotation time (sec)	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.25, ~~0.3,~~ 0.5, 1.0
Gantry Tilt (degree)	N/A	N/A	N/A	+/- 25 +/-30 (only with Vitus)
Maximum temporal resolution in ECG gated or triggered examination (ms)	mono- mono-segment: 66 bi-segment: 33	mono- mono-segment: 66 bi-segment: 33	mono-segment: 66 bi-segment: 33	mono-segment: 125 bi-segment: 66
Maximum scan speed at pitch (mm/s at pitch x)	737 mm/s at pitch 3.2	492 mm/s at pitch 3.2	737 mm/s at pitch 3.2	261 at pitch 1.7
Patient Table Type	Vario 2.D Vitus Installation option with extended distance (Vitus)	Vario 2.D Vitus Installation option with extended distance (Vitus)	Vario 2.D Vitus Installation option with extended distance (Vitus)	Vario RT Vitus Vario 2.D
Max. Scan length Topogram (mm)	Vario 2.D: 2080 Vitus: 2080	Vario 2.D: 2080 Vitus: 2080	Vario 2.D: 2080 Vitus: 2080	Vario 2.D: 2080 Vitus: 2080 Vario RT: 1680
Max. Scan length Image acquisition (mm)	Vario 2.D: 2000 Vitus: 2000	Vario 2.D: 2000 Vitus: 2000	Vario 2.D: 2000 Vitus: 2000	Vario 2.D: 2000 Vitus: 2000 Vario RT: 1600

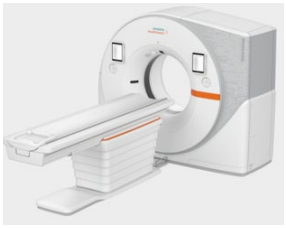
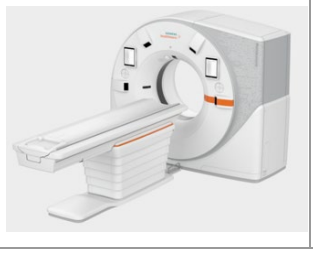
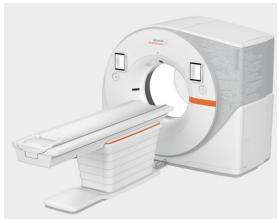
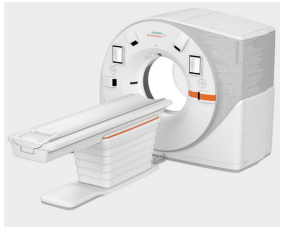
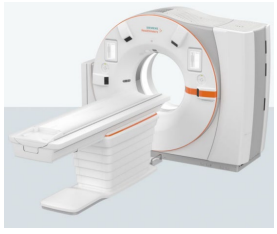
Hardware property	Subject device (Dual source NAEOTOM CT systems)		Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Patient table Max. weight capacity (kg)	Vario 2.D: 307 Vitus: 307 or 340	Vario 2.D: 307 Vitus: 340	Vario 2.D: 307 Vitus: 307 or 340	Vario 2.D: 307 Vitus: 307 Vario RT: 227
Spectral filtration	Tin Filter for both tubes: 0.4 mm additional Tin Filter for the smaller tube-detector system (B-system) only: 0.7 mm	Tin Filter for both tubes: 0.4 mm additional Tin Filter for the smaller tube-detector system (B-system) only: 0.7 mm	Tin Filter for both tubes: 0.4 mm additional Tin Filter for the smaller tube-detector system (B-system) only: 0.7 mm	Combined Tin Filter / Split Filter, and extra Tin Filter
FAST 3D Camera	option for patient positioning with FAST 3D Camera installation options: • ceiling mounted	option for patient positioning with FAST 3D Camera installation options: • ceiling mounted	option for patient positioning with FAST 3D Camera installation options: • ceiling mounted	option for patient positioning with FAST 3D Camera installation options: • ceiling mounted
X-ray foot switch	Option to trigger hands-free scanning	Option to trigger hands-free scanning	Option to trigger hands-free scanning	Option to trigger hands-free scanning
Table foot switch	Option for table patient movement	Option for table patient movement	Option for table patient movement	Option for table patient movement
Tablet dock for patient table	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.
Interventional Joystick (IVJ)	Option to move the table during myNeedle Guide procedures in the examination room. electrical connection for the tablet dock which allows charging the tablet when mounted.	Option to move the table during myNeedle Guide procedures in the examination room. electrical connection for the tablet dock which allows charging the tablet when mounted.	Option to move the table during myNeedle Guide procedures in the examination room. electrical connection for the tablet dock which allows charging the tablet when mounted.	Option to move the table during myNeedle Guide procedures in the examination room. electrical connection for the tablet dock which allows charging the tablet when mounted.

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Laser supported workflow	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions
CARE Moodlight	LED lights integrated on the gantry front to indicate the system status: • System startup • Scan countdown • Radiation on	LED lights integrated on the gantry front to indicate the system status: • System startup • Scan countdown • Radiation on	n.a.[6]	n.a.[6]
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	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system • Varian RGSC respiratory gating system • Open interface compatible	n.a.	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system • Varian RGSC respiratory gating system • Open interface compatible

[6] CARE Moodlight is cleared in K233650 for the SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.Top and SOMATOM go.All. K233650 is a bundle 510(k) including the SOMATOM go. Platform (SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim and SOMATOM go.Open Pro) and the SOMATOM X. Platform (SOMATOM X.cite and SOMATOM X.ceed).

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
	respiratory gating systems • Open Online Interface	respiratory gating systems • Open Online Interface		respiratory gating systems

Table 4: Hardware characteristics for the single source subject device NAEOTOM Alpha.Prime (software version SOMARIS/10 syngo CT VB20) compared to the predicate devices.

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner
Design	without myNeedle Laser:  with myNeedle Laser: 	without myNeedle Laser:  with myNeedle Laser: 	without myNeedle Laser:  with myNeedle Laser: 

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
System configuration	Single Source	Dual Source	Single Source
Environment of Use	Professional Healthcare Facility	Professional Healthcare Facility	Professional Healthcare Facility
Generator max. power (kW)	105 or 120	2x 120	105 or 120
Detector technology	QuantaMax Direct Conversion with "Quantum Technology"	QuantaMax Direct Conversion with "Quantum Technology"	UFC (Ultra Fast Ceramic)
Detector volume coverage (mm)	57.6	2x 57.6	38.4
Detector physical rows	288	2x 288	64
Detector slice width (mm)	0.2	0.2	0.6
Detector DAS channel no.	2752	2752 (A system) 1984 (B system)	920
Tube technology	VECTRON	VECTRON	VECTRON
Tube kV steps	70, 90, 100, 120, 140	70, 90, 100, 120, 140, 150 (150 kV only available on the smaller tube-detector system (B system) and only in combination with the	70, 80, 90, 100, 110, 120, 130, 140, 150

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
		additional Sn filter, 0.7 mm)	
Tube max. current (mA)	1200 (for 105 kW Generator) 1300 (for 120 kW Generator)	2x 1300	1200 (for 105 kW Generator) 1300 (for 120 kW Generator)
Tube tube focus (mm)	0.4 x 0.5/8° 0.6 x 0.7/8° 0.8 x 1.1/8°	0.4 x 0.5/8° 0.6 x 0.7/8° 0.8 x 1.1/8° (for both tubes)	0.4 x 0.5/8° 0.6 x 0.7/8° 0.8 x 1.1/8°
Tube heat capacity	higher than 30 MHU	higher than 30 MHU	higher than 30 MHU
Tube cooling rate (MHU/min)	2.7	2.7	2.7
Gantry bore size (cm)	82	82	82
Gantry Scan FoV (cm)	50	50	50
Gantry Extended FoV (cm)	81.5	81.5	81.5
Gantry rotation time (sec)	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.25, 0.3, 0.5, 1.0
Gantry Tilt (degree)	N/A	N/A	+/- 25 +/-30 (only with Vitus)

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Maximum temporal resolution in ECG gated or triggered examination (ms)	mono-segment: 125 bi-segment: 66	mono-segment: 66 bi-segment: 33	mono-segment: 125 bi-segment: 66
Maximum scan speed at pitch (mm/s at pitch x)	345 mm/s at pitch 1.5	737 mm/s at pitch 3.2	261 mm/s at pitch 1.7
Patient Table Type	Vario 2.D Vitus Installation option with extended distance (Vitus)	Vario 2.D Vitus Installation option with extended distance (Vitus)	Vario RT Vario 2.D Vitus
Max. Scan length Topogram (mm)	Vario 2.D: 2080 Vitus: 2080	Vario 2.D: 2080 Vitus: 2080	Vario RT: 1680 Vario 2.D: 2080 Vitus: 2080
Max. Scan length Image acquisition (mm)	Vario 2.D: 2000 Vitus: 2000	Vario 2.D: 2000 Vitus: 2000	Vario RT: 1600 Vario 2.D: 2000 Vitus: 2000
Patient table Max. weight capacity (kg)	Vario 2.D: 307 Vitus: 340	Vario 2.D: 307 Vitus: 307 or 340	Vario RT: 227 Vario 2.D: 307 Vitus: 307 or 340
Spectral filtration	Tin Filter: 0.4 mm	Tin Filter for both tubes: 0.4 mm additional Tin Filter for the smaller tube-detector system (B-system) only: 0.7 mm	Combined Tin Filter / Split Filter, and extra Tin Filter

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
FAST 3D Camera	option for patient positioning with FAST 3D Camera installation options: • ceiling mounted	option for patient positioning with FAST 3D Camera installation options: • ceiling mounted	option for patient positioning with FAST 3D Camera installation options: • ceiling mounted
X-ray foot switch	Option to trigger hands-free scanning	Option to trigger hands-free scanning	Option to trigger hands-free scanning
Table foot switch	Option for table patient movement	Option for table patient movement	Option for table patient movement
Tablet dock for patient table	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.
Interventional Joystick (IVJ)	Option to move the table during myNeedle Guide procedures in the examination room. electrical connection for the tablet dock which allows charging the tablet when mounted.	Option to move the table during myNeedle Guide procedures in the examination room. electrical connection for the tablet dock which allows charging the tablet when mounted.	Option to move the table during myNeedle Guide procedures in the examination room. electrical connection for the tablet dock which allows charging the tablet when mounted.
Laser supported workflow	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
CARE Moodlight	LED lights integrated on the gantry front to indicate the system status: • System startup • Scan countdown • Radiation on	n.a.[7]	n.a.[7]
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 • Open Online Interface	n.a.	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system • Varian RGSC respiratory gating system • Open interface compatible respiratory gating systems
Power Shaver	energy storage assembly to reduce mains peak current towards mains	n.a.	n.a.

[7] CARE Moodlight is cleared in K233650 for the SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.Top and SOMATOM go.All. K233650 is a bundle 510(k) including the SOMATOM go. Platform (SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim and SOMATOM go.Open Pro) and the SOMATOM X. Platform (SOMATOM X.cite and SOMATOM X.ceed).

Table 5: Software characteristics for the dual source subject devices NAEOTOM Alpha and NAEOTOM Alpha.Pro and single source subject device NAEOTOM Alpha.Prime (software version SOMARIS/10 syngo CT VB20) compared to the predicate devices.

Software property	**Subject device** **(Dual Source)**	**Subject device** **(Single Source)**	**Primary predicate device**	**Secondary predicate device**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Operating System	Windows based SOMARIS/10 *syngo* CT VB20 Note: the short version *syngo* CT VB20 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VB20 Note: the short version *syngo* CT VB20 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VB10 Note: the short version *syngo* CT VB10 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VB10 Note: the short version *syngo* CT VB10 is also used as labeling information
Workplace	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function
Standard system software	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network	• *syngo* Examination • *syngo* Viewing • *syngo* Filming • *syngo* Archiving & Network
Detector firmware	QuantaMax detector firmware supported	QuantaMax detector firmware supported	QuantaMax detector firmware supported	Stellar detector firmware supported
Teamplay	Support of teamplay Protocols	Support of teamplay Protocols	Support of teamplay Protocols	Support of teamplay Protocols

Software property	Subject device (Dual Source)	Subject device (Single Source)	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
Protocols	Support of: • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition • Protocols supporting CT Intervention, Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD - Quantum HD Cardiac - Quantumpeak • Dynamic imaging (Flex 4D	Support of: • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition • Protocols supporting CT Intervention, Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD - Quantum HD Cardiac • Dynamic imaging (Flex 4D	Support of: • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition • Protocols supporting CT Intervention, Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD - Quantum HD Cardiac - Quantumpeak • Dynamic imaging (Flex 4D	Support of: • 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) • Protocols supporting CT Intervention, Cardiac Scanning

Software property	Subject device (Dual Source)	Subject device (Single Source)	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
	Spiral with separation factor driven scan range) • Protocols for Radiation Therapy Planning support patient marking • Protocols for DirectBreathhold • Protocols for FAST 4D • Protocols that allow scanning with support of an external respiratory gating system (Anzai, Varian RGSC, Open interface, Open Online Interface)	Spiral with separation factor driven scan range) • Protocols for Radiation Therapy Planning support patient marking • Protocols for DirectBreathhold • Protocols for FAST 4D • Protocols that allow scanning with support of an external respiratory gating system (Anzai, Varian RGSC, Open interface, Open Online Interface)	Spiral with cycle time driven scan range)	• Dynamic imaging (Flex 4D Spiral Flex 4D Spiral with cycle time driven scan range) • Protocols for Radiation Therapy Planning support patient marking • Protocols for DirectBreathhold • Protocols for FAST 4D • Protocols that allow scanning with support of an external respiratory gating system (ANZAI, Varian RGSC, Open interface)
Advanced Reconstruction	Recon&GO: - Spectral Recon - Inline Results – DE SPP - Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges	Recon&GO: - Spectral Recon - Inline Results – DE SPP - Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges	Recon&GO: - Spectral Recon - Inline Results – DE SPP - Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges	Recon&GO: - Spectral Recon - Inline Results – DE SPP - Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges

Software property	Subject device (Dual Source)	Subject device (Single Source)	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha NAEOTOM Alpha.Pro SOMARIS/10 *syngo* CT VB20	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10 (K233657)	SOMATOM X.ceed SOMARIS/10 *syngo* CT VB10 (K233650)
	- Inline Results – table and bone removal	- Inline Results – table and bone removal	- Inline Results – table and bone removal	- Inline Results – table and bone removal
Image viewing	CT View&GO: - 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 table and bone removal	CT View&GO: - 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 table and bone removal	CT View&GO: - 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 table and bone removal	CT View&GO: - 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 table and bone removal
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, Inline Results – RT-Planning introduced	• 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, Inline Results – RT-Planning introduced	• 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	• 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, including the interface Inline Results – RT-Planning

Software property	Subject device (Dual Source)	Subject device (Single Source)	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
	• CT View&GO plug-in interface: designed for standalone plug-ins which are represented by the cleared medical device by its own called syngo.CT Extended Functionality, plug-in CT View&GO – Sim&GO introduced	• CT View&GO plug-in interface: designed for standalone plug-ins which are represented by the cleared medical device by its own called syngo.CT Extended Functionality, plug-in CT View&GO – Sim&GO introduced	• CT View&GO plug-in interface: designed for standalone plug-ins which are represented by the cleared medical device by its own called syngo.CT Extended Functionality	• CT View&GO plug-in interface: designed for standalone plug-ins which are represented by the cleared medical device by its own called syngo.CT Extended Functionality, including the plug-in CT View&GO – Sim&GO
	• CT View&GO software interface for Advanced Visualization Apps: 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.	• CT View&GO software interface for Advanced Visualization Apps: 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.	• CT View&GO software interface for Advanced Visualization Apps: 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	• CT View&GO software interface for Advanced Visualization Apps: 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

Software property	Subject device (Dual Source)	Subject device (Single Source)	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
	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.	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.	are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners.	are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners.
Cybersecurity	IT Hardening	IT Hardening	IT Hardening	IT Hardening
HD FoV	supported	supported	supported	supported
Standard technologies	• FAST technologies • CARE technologies • GO technologies • CARE keV	• FAST technologies • CARE technologies • GO technologies • CARE keV	• FAST technologies • CARE technologies • GO technologies • CARE keV	• FAST technologies • CARE technologies • GO technologies • CARE kV
Respiratory Motion management (workflows)	Workflows for respiration-correlated scans for radiation therapy planning: - FAST 4D - Direct i4D - DirectBreathhold	Workflows for respiration-correlated scans for radiation therapy planning: - FAST 4D - Direct i4D - DirectBreathhold	n.a.	Workflows for respiration-correlated scans for radiation therapy planning: - FAST 4D - Direct i4D - DirectBreathhold
Direct Laser Steering	software interface to control 3rd party lasers (LAP lasers) to support a markerless workflow for patient marking in	software interface to control 3rd party lasers (LAP lasers) to support a markerless workflow for patient marking in	n.a.	software interface to control 3rd party lasers (LAP lasers) to support a markerless workflow for patient marking in

Software property	Subject device (Dual Source)	Subject device (Single Source)	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
	radiation therapy planning (RTP).	radiation therapy planning (RTP).		radiation therapy planning (RTP).
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 • Collision Indication • Centerline/ Grid Overlay	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction
DirectSetup Notes	patient and accessory setup documentation in the Scan&GO workflow	patient and accessory setup documentation in the Scan&GO workflow	n.a.	n.a.
Oncology exchange	transfer of prescription information from the ARIA Oncology Information System (OIS) to the CT scanner	transfer of prescription information from the ARIA Oncology Information System (OIS) to the CT scanner	n.a.	n.a.
FAST Planning	detects globally used scan and recon ranges from the topogram image additional body regions: - Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee	detects globally used scan and recon ranges from the topogram image additional body regions: - Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee	detects globally used scan and recon ranges from the topogram image	detects globally used scan and recon ranges from the topogram image

Software property	Subject device (Dual Source)	Subject device (Single Source)	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (K233657)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VB10 (K233650)
	- Neck and chest - Neck and Lung - Extremities – Both knees	- Neck and chest - Neck and Lung - Extremities – Both knees		
Eco Power Mode	reduce the energy consumption during idle times.	reduce the energy consumption during idle times.	n.a.	n.a.
Iterative Reconstruction Methods	Quantum Iterative Reconstruction iMAR	Quantum Iterative Reconstruction iMAR	Quantum Iterative Reconstruction iMAR	ADMIRE SAFIRE iMAR
Matrix sizes	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision Matrix)

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation is completed. Test results show that the subject devices, the NAEOTOM CT scanner systems with *syngo* CT VB20, 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 subject devices NAEOTOM CT scanner systems during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

The general purpose of each 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 for new and modified features**
Direct i4D	The target of the bench test is to perform a respiratory sequence scan using a dynamic phantom where at every planned position of the scan range at least one complete breathing cycle is acquired. Objective of the test is to compare a conventional respiratory 4DCT scan (spiral scan) with the breathing pattern of a thorax phantom and the result of Direct i4D with the same breathing pattern. The test results show that with Direct i4D it is possible to acquire data for a full breathing cycle at every position of the patient even if the respiratory rate changes during the data acquisition. Compared to the conventional 4DCT scan mode interpolation artifacts (which occur because not for every position a complete breathing cycle could be acquired) can successfully be avoided with Direct i4D.
DirectBreathhold	The test results show that using the Direct Breathhold functionality, a spiral scan can automatically be triggered from an external respiratory gating device. The actual scan remains unchanged, and the object is correctly depicted in the resulting image.
Recon&GO – RT planning	The bench test underpins the possibility that with the introduction of the RTP scan protocols in the subject devices NAEOTOM CT scanner systems with syngo CT VB20, time and imaging dose can be saved, since each RTP scan range allows for spectral post-processing to provide task-specific images for an end-to-end radiotherapy workflow and thus no additional scan range with Single Energy is needed.

Feature/Non-clinical supportive testing	Bench Testing performed for new and modified features
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.
Flex 4D Spiral	The performed bench test report describes the technical background of Flex 4D Spiral and its functionalities with NAEOTOM CT scanners, demonstrate the proper function of those, and assess the image quality of Flex 4D Spiral.
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.
Low-Dose Lung Cancer Screening – NAEOTOM Alpha.Pro	The bench test provides a comparison of technical parameters specific to Low-Dose Lung Cancer Screening of the predicate and subject devices, following the established concept of our previous 510(k) submissions. It can be concluded that the subject and predicate devices are substantially equivalent for the task of Low-Dose Lung Cancer Screening since the bench test results showed comparable technical parameters.
Low-Dose Lung Cancer Screening – NAEOTOM Alpha.Prime	The bench test provides a comparison of technical parameters specific to Low-Dose Lung Cancer Screening of the predicate and subject devices, following the established concept of our previous 510(k) submissions. It can be concluded that the subject and predicate devices are substantially equivalent for the task of Low-Dose Lung Cancer Screening since the bench test results showed comparable technical parameters.

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
12/19/2022	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
01/14/2014	12-269	IEC	60601-1-3 Edition 2.1 2013-04	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
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 processes [Including Amendment 1 (2016)]
		IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
07/09/2014	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)]
09/17/2018	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

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
		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
12/23/2016	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	Medical electrical equipment - Medical image display systems

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
			CONSOLIDATED VERSION	- 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]
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	10/05/2022
Refuse to Accept Policy for 510(k)s	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 Device Software Functions	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

FDA Guidance Document	Issue date
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 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 NAEOTOM Alpha 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

The non-clinical data supports the safety of the devices and the hardware and software verification and validation demonstrates that the NAEOTOM CT scanner systems perform as intended in the specified use conditions. Verification and validation, clinical/patient and phantom testing were performed. The data included in this submission demonstrates that the NAEOTOM CT scanner systems with described modifications performs comparably to the predicate devices currently marketed for the same intended use. The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject devices are as safe, as effective, and perform as well as or better than the predicate devices.