July 28, 2025

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

Re: K251061
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: April 4, 2025
Received: April 4, 2025

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,

for

Lu Jiang
Assistant Director
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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.

510(k) Number *(if known)*
K251061

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.

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K251061

510(k) Summary
for
NAEOTOM Alpha class CT Scanner Systems
with software version SOMARIS/10 *syngo* CT VB20 (update)

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

Predicate Device:

Trade Name:	NAEOTOM Alpha class CT systems with SOMARIS/10 *syngo* CT VB20
510(k) Number:	K243523
Clearance Date:	February 12, 2025
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All predicate device recalls have been considered in the subject device design.

Note: K243523 was a bundled 510(k) including the NAEOTOM Alpha Alpha (trade name ex-factory: NAEOTOM Alpha.Peak; trade name installed base: NAEOTOM Alpha), NAEOTOM Alpha.Pro, and NAEOTOM Alpha.Prime.

IV. Device Description

Siemens intends to update the software version *syngo* CT VB20 (update) for the following NAEOTOM Alpha class CT systems:

Dual Source NAEOTOM CT scanner systems:

- NAEOTOM Alpha
  (trade name ex-factory CT systems: NAEOTOM Alpha.Peak; trade name of installed base CT systems with SW upgrade only: NAEOTOM Alpha)

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

- NAEOTOM Alpha.Pro

Single Source NAEOTOM CT scanner system:

- NAEOTOM Alpha.Prime

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 (update) 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 (update) is a Computed Tomography X-ray system which features one continuously rotating tube-detector systems, denominated as A-system (single source NAEOTOM 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 Alpha class CT scanner systems".

The NAEOTOM Alpha class CT scanner systems with SOMARIS/10 *syngo* CT VB20 (update) 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 is not limited to, Brachytherapy, Particle Therapy 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 Alpha class CT scanner systems is *syngo* CT VB20 (update) (SOMARIS/10 *syngo* CT VB20 (update)). 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 (update) (SOMARIS/10 *syngo* CT VB20 (update)) shall support additional software features compared to the software version of the predicate devices NAEOTOM Alpha class CT systems with *syngo* CT VB20 (SOMARIS/10 *syngo* CT VB20) cleared in K243523.

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

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 predicate device Indications for Use (K243523).

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 (update) software version is a further development of the SOMARIS/10 *syngo* CT VB20 software version which is cleared in K243523.

The subject devices NAEOTOM CT scanner systems with SOMARIS/10 *syngo* CT VB20 (update) 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 Alpha class 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 (update) software reuses all unmodified software features of the legacy software *syngo* CT VB20 cleared in K243523. Additionally, no features present in the predicate device are descoped.

Software version SOMARIS/10 *syngo* CT VB20 (update) 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 class CT scanner systems 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 Alpha class CT scanner systems with SOMARIS/10 *syngo* CT VB20 (update) will support 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 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
n.a.	The feature is not supported by the subject device or by the 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 (update) compared to the predicate devices.

	Technological property	**HW/ SW change**	**Subject devices**		**Predicate devices**	
			Dual Source	Single Source	Dual Source	Single Source
			NAEOTOM Alpha **NAEOTOM Alpha.Pro** *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** *syngo* CT VB10 (K243523)
1.	HD FoV 5.0	SW	**new**	**new**	n.a.	n.a.
2.	ZeeFree RT	SW	**new**	**new**	n.a.	n.a.
3.	myExam Contrast	SW	**new**	**new**	n.a.	n.a.

A tabular summary of the comparable hardware and software properties between the subject devices NAEOTOM Alpha class CT scanner systems with software version *syngo* CT VB20 (update) and the predicate devices are listed in the following tables (modifications are in gray shaded sections).

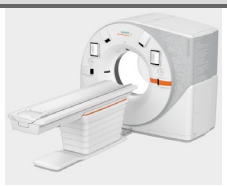
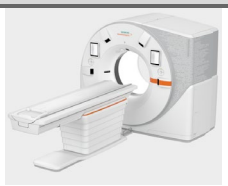
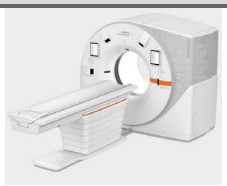
Table 3 compares the hardware properties of the dual source subject devices NAEOTOM Alpha (trade name ex-factory: NAEOTOM Alpha.Peak; trade name installed base: NAEOTOM Alpha) and NAEOTOM Alpha.Pro with the predicate devices.

Table 4 provides a comparison of the hardware properties between the single source subject device NAEOTOM Alpha.Prime and the 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 (update) compared to the predicate devices.

Hardware property	**Subject device** (Dual source NAEOTOM CT systems)		**Predicate devices** (Dual source NAEOTOM CT systems)	
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)
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	NAEOTOM Alpha.Pro
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: NAEOTOM Alpha.Pro	• Ex-factory CT systems: NAEOTOM Alpha.Peak • Installed base CT systems: NAEOTOM Alpha	• Ex-factory CT systems: NAEOTOM Alpha.Pro • Installed base CT systems: NAEOTOM Alpha.Pro
Design	without myNeedle Laser:  with myNeedle Laser:	without myNeedle Laser:  with myNeedle Laser:	without myNeedle Laser:  with myNeedle Laser:	without myNeedle Laser:  with myNeedle Laser:

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Predicate devices (Dual source NAEOTOM CT systems)	
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)
				
System configuration	Dual Source	Dual Source	Dual Source	Dual 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	2x 120
Detector technology	QuantaMax direct conversion with “Quantum Technology”	QuantaMax direct conversion with “Quantum Technology”	QuantaMax direct conversion with “Quantum Technology”	QuantaMax direct conversion with “Quantum Technology”
Detector volume coverage (mm)	2x 57.6	2x 38.4	2x 57.6	2x 38.4
Detector physical rows	2x 288	2x 192	2x 288	2x 192
Detector slice width (mm)	0.2	0.2	0.2	0.2
Detector DAS channel no.	2752 (A system) 1984 (B system)	2752 (A system) 1984 (B system)	2752 (A system) 1984 (B system)	2752 (A system) 1984 (B system)
Tube technology	VECTRON	VECTRON	VECTRON	VECTRON

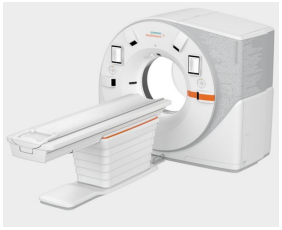
Hardware property	Subject device (Dual source NAEOTOM CT systems)		Predicate devices (Dual source NAEOTOM CT systems)	
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)
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, 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)
Tube max. current (mA)	2x 1300	2x 1300	2x 1300	2x 1300
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° (for both tubes)
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 Extended FoV (cm)	81.5	81.5	81.5	81.5

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Predicate devices (Dual source NAEOTOM CT systems)	
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)
Gantry rotation time (sec)	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.25, 0.5, 1.0
Gantry Tilt (degree)	N/A	N/A	N/A	N/A
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- mono-segment: 66 bi-segment: 33	mono- mono-segment: 66 bi-segment: 33
Maximum scan speed at pitch (mm/s at pitch x)	737 mm/s at pitch 3.2	491 mm/s at pitch 3.2	737 mm/s at pitch 3.2	491 mm/s at pitch 3.2
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 2.D Vitus Installation option with extended distance (Vitus)
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
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
Patient table	Vario 2.D: 307	Vario 2.D: 307	Vario 2.D: 307	Vario 2.D: 307

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Predicate devices (Dual source NAEOTOM CT systems)	
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)
Max. weight capacity (kg)	Vitus: 307 or 340	Vitus: 340	Vitus: 307 or 340	Vitus: 340
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	Tin Filter for both tubes: 0.4 mm additional Tin Filter for the smaller tube-detector system (B-system) only: 0.7 mm
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.
Laser supported workflow	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter

Hardware property	Subject device (Dual source NAEOTOM CT systems)		Predicate devices (Dual source NAEOTOM CT systems)	
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)
	position; myNeedle Laser visualizes a planned needle path for interventions	position; myNeedle Laser visualizes a planned needle path for interventions	position; myNeedle Laser visualizes a planned needle path for interventions	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 • Scan	LED lights integrated on the gantry front to indicate the system status: • System startup • Scan countdown • Scan	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
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	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	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	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

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

Hardware property	**Subject device** (Single source NAEOTOM CT system)	**Predicate device** (Single source NAEOTOM CT system)
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
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: 
System configuration	Single Source	Single Source
Environment of Use	Professional Healthcare Facility	Professional Healthcare Facility
Generator max. power (kW)	105 or 120	105 or 120
Detector technology	QuantaMax Direct Conversion with “Quantum Technology”	QuantaMax Direct Conversion with “Quantum Technology”
Detector volume coverage (mm)	57.6	57.6
Detector	288	288

Hardware property	Subject device (Single source NAEOTOM CT system)	Predicate device (Single source NAEOTOM CT system)
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
physical rows		
Detector slice width (mm)	0.2	0.2
Detector DAS channel no.	2752	2752
Tube technology	VECTRON	VECTRON
Tube kV steps	70, 90, 100, 120, 140	70, 90, 100, 120, 140
Tube max. current (mA)	1200 (for 105 kW Generator) 1300 (for 120 kW Generator)	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°
Tube heat capacity	higher than 30 MHU	higher than 30 MHU
Tube cooling rate (MHU/min)	2.7	2.7
Gantry bore size (cm)	82	82
Gantry Scan FoV (cm)	50	50
Gantry Extended FoV (cm)	81.5	81.5

Hardware property	Subject device (Single source NAEOTOM CT system)	Predicate device (Single source NAEOTOM CT system)
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
Gantry rotation time (sec)	0.25, 0.5, 1.0	0.25, 0.5, 1.0
Gantry Tilt (degree)	N/A	N/A
Maximum temporal resolution in ECG gated or triggered examination (ms)	mono-segment: 125 bi-segment: 66	mono-segment: 125 bi-segment: 66
Maximum scan speed at pitch (mm/s at pitch x)	345 mm/s at pitch 1.5	345 mm/s at pitch 1.5
Patient Table Type	Vario 2.D Vitus Installation option with extended distance (Vitus)	Vario 2.D Vitus Installation option with extended distance (Vitus)
Max. Scan length Topogram (mm)	Vario 2.D: 2080 Vitus: 2080	Vario 2.D: 2080 Vitus: 2080
Max. Scan length Image acquisition (mm)	Vario 2.D: 2000 Vitus: 2000	Vario 2.D: 2000 Vitus: 2000
Patient table Max. weight capacity (kg)	Vario 2.D: 307 Vitus: 340	Vario 2.D: 307 Vitus: 340
Spectral filtration	Tin Filter: 0.4 mm	Tin Filter: 0.4 mm
FAST 3D Camera	option for patient positioning with FAST 3D Camera	option for patient positioning with FAST 3D Camera

Hardware property	Subject device (Single source NAEOTOM CT system)	Predicate device (Single source NAEOTOM CT system)
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	installation options: • ceiling mounted	installation options: • ceiling mounted
X-ray foot switch	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
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.
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.
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
CARE Moodlight	LED lights integrated on the gantry front to indicate the system status: • System startup • Scan countdown • Scan	LED lights integrated on the gantry front to indicate the system status: • System startup • Scan countdown • Radiation on
Respiratory Motion management - Interfaces for respiratory gating	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system • Varian RGSC respiratory gating system • Open interface compatible respiratory gating systems	acquisition of respiration-correlated scans supported Interface connectors for: • Anzai respiratory gating system • Varian RGSC respiratory gating system • Open interface compatible respiratory gating systems

Hardware property	Subject device (Single source NAEOTOM CT system)	Predicate device (Single source NAEOTOM CT system)
	NAEOTOM Alpha.Prime SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	• Open Online Interface	• Open Online Interface
Power Shaver	energy storage assembly to reduce mains peak current towards mains	energy storage assembly to reduce mains peak current towards mains

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

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
Operating System	Windows based SOMARIS/10 *syngo* CT VB20 (update) (with additional software features) Note: the short version *syngo* CT VB20 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VB20 (update) (with additional software features) 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 VB20 Note: the short version *syngo* CT VB20 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	*syngo* Acquisition Workplace (ICS) named as “myExam Console” Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as “myExam	*syngo* Acquisition Workplace (ICS) named as “myExam Console” Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as “myExam Satellite” with	*syngo* Acquisition Workplace (ICS) named as “myExam Console” Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as “myExam

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	Remote Recon function	Satellite" with Remote Recon function	Remote Recon function	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	QuantaMax detector firmware supported
Teamplay	Support of teamplay Protocols	Support of teamplay Protocols	Support of teamplay Protocols	Support of teamplay Protocols
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	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	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	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

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD - Quantum HD Cardiac - Quantumpeak • Dynamic imaging (Flex 4D 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)	with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD • Dynamic imaging (Flex 4D 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)	with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD - Quantum HD Cardiac - Quantumpeak • Dynamic imaging (Flex 4D 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)	with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD • Dynamic imaging (Flex 4D 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)
Advanced Reconstruction	Recon&GO: - Spectral Recon - Inline Results – DE SPP	Recon&GO: - Spectral Recon - Inline Results – DE SPP	Recon&GO: - Spectral Recon - Inline Results – DE SPP	Recon&GO: - Spectral Recon - Inline Results – DE SPP

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	- Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges - Inline Results – table and bone removal	- Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges - Inline Results – table and bone removal	- Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges - Inline Results – table and bone removal	- Inline Results – Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Results – Spine and Rib Ranges - 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	• Recon&GO Inline Results: Software interface to post-processing algorithms which are unmodified when loaded onto the CT	• Recon&GO Inline Results: Software interface to post-processing algorithms which are unmodified when loaded onto the CT	• Recon&GO Inline Results: Software interface to post-processing algorithms which are unmodified when loaded onto the CT

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	scanners and 510(k) cleared as medical devices, Inline Results – RT-Planning 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 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	scanners and 510(k) cleared as medical devices, Inline Results – RT-Planning 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 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	scanners and 510(k) cleared as medical devices, Inline Results – RT-Planning 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 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	scanners and 510(k) cleared as medical devices, Inline Results – RT-Planning 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 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

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners.	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 by Computed Tomography scanners.	is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners.	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 by Computed Tomography scanners.
Cybersecurity	IT Hardening	IT Hardening	IT Hardening	IT Hardening
HD FoV	HD FoV 4.0 HD FoV 5.0	HD FoV 4.0 HD FoV 5.0	HD FoV 4.0	HD FoV 4.0
Standard techno-logies	• 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 keV
Respiratory Motion manage-ment **(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	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

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
Direct Laser Steering	software interface to control 3rd party lasers (LAP lasers) to support a markerless workflow for patient marking in radiation therapy planning (RTP).	software interface to control 3rd party lasers (LAP lasers) to support a markerless workflow for patient marking in radiation therapy planning (RTP).	software interface to control 3rd party lasers (LAP lasers) to support a markerless workflow for patient marking in radiation therapy planning (RTP).	software interface to control 3rd party lasers (LAP lasers) to support a markerless workflow for patient marking in 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 • Collision Indication • Centerline/ Grid Overlay	FAST integrated workflow: • FAST Range • FAST Isocentering • FAST Direction • Collision Indication • Centerline/ Grid Overlay
DirectSetup Notes	patient and accessory setup documentation in the Scan&GO workflow	patient and accessory setup documentation in the Scan&GO workflow	patient and accessory setup documentation in the Scan&GO workflow	patient and accessory setup documentation in the Scan&GO workflow
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	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
FAST Planning	detects globally used scan and recon ranges from the topogram image additional body regions:	detects globally used scan and recon ranges from the topogram image additional body regions:	detects globally used scan and recon ranges from the topogram image additional body regions:	detects globally used scan and recon ranges from the topogram image additional body regions:

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
	- Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung - Extremities – Both knees	- Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung - Extremities – Both knees	- Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung - Extremities – Both knees	- Head/Neck (Vascular), Lateral/APPA - Vascular – Runoff Knee - Neck and chest - Neck and Lung - Extremities – Both knees
Eco Power Mode	reduce the energy consumption during idle times.	reduce the energy consumption during idle times.	reduce the energy consumption during idle times.	reduce the energy consumption during idle times.
Iterative Reconstruction Methods	Quantum Iterative Reconstruction iMAR	Quantum Iterative Reconstruction iMAR	Quantum Iterative Reconstruction iMAR	Quantum Iterative Reconstruction 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)
Stack artifact reduced recon-struction	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations ZeeFree RT: StackRecon types in respiratory-related examinations	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations ZeeFree RT: StackRecon types in respiratory-related examinations	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations	Provides images with reduced stack artifacts after the reconstruction: ZeeFree: StackRecon types in cardiac-related examinations

Software property	Subject devices		Predicate devices	
	Dual Source	**Single Source**	**Dual Source**	**Single Source**
	NAEOTOM Alpha **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (update)	**NAEOTOM Alpha** **NAEOTOM Alpha.Pro** SOMARIS/10 *syngo* CT VB20 (K243523)	**NAEOTOM Alpha.Prime** SOMARIS/10 *syngo* CT VB20 (K243523)
myExam Contrast	exchange of contrast injection parameters, scan and patient parameters	exchange of contrast injection parameters, scan and patient parameters	N/A	N/A

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation are completed. Test results show that the subject devices, the NAEOTOM Alpha class CT scanner systems with *syngo* CT VB20 (update), 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.

Bench Testing:

Additional evaluation tests are performed as bench tests to support the new device or device modification on Non-Clinical Performance Testing as listed in Table 6 below.

Table 6: Non-clinical performance testing (bench testing).

Feature/Non-clinical supportive testing	**Bench Testing performed for new and modified features**
HD FoV 5.0	The bench test contains a detailed description and evaluation of the new HD FoV 5. 0 algorithm for extended field of view reconstruction. Results obtained with the new HD FoV 5. 0 algorithm are compared with its predecessor, the HD FoV 4. 0 algorithm, based on physical and anthropomorphic phantoms. In addition to the bench test, the performance of the algorithm was evaluated by board-approved radio-oncologists and medical physicists by means of retrospective blinded rater study. This comparison is conducted to demonstrate that the HD FoV 5. 0 algorithm is as safe and effective as the HD FoV 4. 0 algorithm.
ZeeFree RT	The bench test evaluates the performance of the ZeeFree RT reconstruction. The objectives of the tests are to demonstrate that compared to the Standard reconstruction, ZeeFree RT • introduces no relevant errors in terms of CT values and noise levels measured in a homogeneous water phantom, *and* • introduces no relevant errors in terms of CT values measured in a phantom with tissue-equivalent inserts, even in the presence of metals and in combination with the iMAR algorithm, *and* • introduces no relevant geometrical distortions in a static torso phantom, *and* • introduces no relevant deteriorations of the position or shape of a dynamic thorax phantom when moving a spherical shape according to regular, irregular, and patient breathing motion. In addition to the bench test, the performance of the algorithm was evaluated by board-approved radio-oncologists and medical physicists by means of retrospective blinded rater studies of respiratory 4D CT examinations performed at two institutions. The bench test results show that the ZeeFree RT reconstruction • can successfully be applied to 4D respiratory-gated sequence images (Direct i4D), *and*

Feature/Non-clinical supportive testing	Bench Testing performed for new and modified features
	• enables the optional reconstruction of stack artefact corrected images, which reduce the strength of misalignment artefacts, if such stack alignment artefacts are identified in non-corrected standard images, *and* • does not introduce relevant new artefacts, which were previously not present in the non-corrected standard reconstruction, *and* • does not affect CT values and noise levels in a homogenous water phantom outside of stack-transition areas compared to the non-corrected standard reconstruction, *and* • can be successfully applied in combination with metal artifact correction (iMAR) and does not introduce new artifacts, which were previously not present in the non-corrected standard reconstruction, even in presence of metals, *and* • can be successfully applied to phantom data if derived from a suitable motion phantom demonstrating its correct technical function on the tested device, *and* • is independent from the physical detector width of the acquired data. By design, input images for the correction part of the algorithm are independent of kernel, slice thickness and increment since those parameters are fixed.

A list of recognized consensus standards and general use consensus standards considered for the subject devices is provided as Table 7 and Table 8 below.

Table 7: Recognized Consensus Standards.

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
12/18/2023	12-352	NEMA	PS 3.1 - 3.20 2023e	Digital Imaging and Communications in Medicine (DICOM) Set
07/06/2020	12-325	NEMA	XR 25-2019	Computed Tomography Dose Check
07/06/2020	12-330	NEMA	XR 28-2018	Supplemental Requirements for User Information and System Function Related to Dose in CT
12/23/2019	12-328	IEC	61223-3-5 Edition 2.0 2019-09	Evaluation and routine testing in medical imaging departments -

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				Part 3-5: Acceptance tests and constancy tests - Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
03/14/2011	12-226	IEC	61223-2-6 Second Edition 2006-11	Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment
06/07/2021	12-336	IEC	60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
06/27/2016	12-302	IEC	60601-2-44 Edition 3.2: 2016	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
12/23/2019	5-125	ANSI AAMI ISO	14971: 2019	Medical devices - Applications of risk management to medical devices
		ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
01/14/2019	13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment

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

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				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]
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
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 class CT scanner systems 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 Alpha class 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 Alpha class CT scanner systems with described modifications performs comparably to the predicate devices currently marketed for the same intended use. The conclusions drawn from the non-clinical and clinical tests demonstrate that the subject devices are as safe, as effective, and perform as well as or better than the predicate devices.