July 12, 2022

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

Re: K220814
Trade/Device Name: NAEOTOM Alpha, Scan&GO Software
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: June 8, 2022
Received: June 9, 2022

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 (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 located 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.

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 803) for

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

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

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220814

Device Name
NAEOTOM Alpha
Scan&GO Software

Indications for Use *(Describe)*

NAEOTOM Alpha
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.

Scan&GO
This in-room scan application is a planning and information system designed to perform the necessary functions required for planning and controlling scans of supported SIEMENS CT scanners. It allows users to work in close proximity to the scanner.

The in-room scan application runs on standard information technology hardware and software, utilizing the standard information technology operating systems and user interface. Communication and data exchange are done using special protocols.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

FOR

NAEOTOM ALPHA CT SCANNER SYSTEM

SOFTWARE VERSION SOMARIS/10 *syngo* CT VA50

(K220814)

Submitted by:
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932
Date Prepared: March 18, 2022

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 Healthcare GmbH
Siemensstr. 1
D-91301 Forchheim, Germany
Establishment Registration Number
3004977335

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

Contact Person:
Tabitha Estes
Regulatory Affairs
Siemens Medical Solutions USA, Inc.
(865) 804-4553 (work cell)
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tabitha.estes@Siemens-healthineers.com

II. Device Name and Classification

Product Name:	NAEOTOM Alpha
Trade Name:	NAEOTOM Alpha
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Product Name:	Scan&GO
Propriety Trade Name:	Scan&GO
Classification Name:	Computed Tomography X-ray System
Secondary Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Secondary CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	JAK
Secondary Product Code:	LLZ

III. Predicate Device

Primary Predicate Device:

Trade Name:	NAEOTOM Alpha, Scan&GO
510(k) Number:	K211591
Clearance Date:	September 30, 2021
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, Scan&GO
510(k) Number:	K211373
Clearance Date:	August 27, 2021
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: K211373 was a bundle submission with various Siemens CT Scanner Systems, including SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite, SOMATOM X.ceed and Scan&GO software.

In this submission, the primary predicate device NAEOTOM Alpha with software version SOMARIS/10 *syngo* CT VA40 and the secondary predicate device SOMATOM X.ceed, both including Scan&GO, are being used, to demonstrate substantial equivalence of technological characteristics.

IV. Device Description

Siemens intends to update software version, SOMARIS/10 *syngo* CT VA50 for Siemens NAEOTOM Alpha Scanner Systems with unmodified mobile workflow options.

This update also includes optional hardware for CT guided intervention workflow.

Dual Source CT Scanner System:

- NAEOTOM Alpha
- Scan&GO Mobile Medical Application (optional mobile workflow component)

The subject device NAEOTOM Alpha with SOMARIS/10 *syngo* CT VA50 is a dual source Computed Tomography (CT) x-ray system featuring two detectors based on photon counting technology.

The CT scanner system algorithm is designed to allow image reconstruction by using photon counting data generated by the subject device. The reconstruction results are comparable with the primary and secondary predicate devices, but support with improved technological characteristics as described in Section 10.

The NAEOTOM Alpha with Software SOMARIS/10 *syngo* CT VA50 produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens and other vendors as an aid in diagnosis and treatment as well as for diagnostic and therapeutic interventions. The computer system delivered with the CT scanner is able to run optional post processing applications.

The Scan&GO mobile workflow is an optional planning and information software designed to perform the necessary functions required for planning and controlling of the workflow of the NAEOTOM Alpha. Scan&GO can be operated on a Siemens provided various tablet hardware that meets certain minimum technical requirements. It allows users to work in close proximity to the scanner and the patient. Specifically Scan&GO allows control/display of the following software interactions via a wireless tablet or personal computer with Wi-Fi connection that meets certain minimum requirements:

- Selection of patients
- Selection of pre-defined protocols
- Scan parameter display
- Patient table position display and gantry tilt parameter display
- Tools and instruction message area,
- Patient table position planning area
- Physiological data display
- Patient data display (e.g. date of birth, name)
- Display of acquired topogram and tomogram images
- Finalization of exam (close patient)
- Mobile Organizer
- Patient Instruction Language (“API languages”)

- predefined workflow associated question/answer dialog

NOTE: Scan&GO does not support storage of images. Additionally, Scan&GO cannot trigger a scan or radiation release.

The software version for the NAEOTOM Alpha, *syngo* CT VA50 (SOMARIS/10 *syngo* CT VA50), 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 a software plugin interface that allows for the use of specific commercially available post processing software algorithms in an unmodified form from the cleared stand-alone post processing version.

New software version *syngo* CT VA50 (SOMARIS/10 *syngo* CT VA50) is a modified software version based on *syngo* CT VA40 (SOMARIS/10 *syngo* CT VA40) which was cleared for the primary predicate device in K211591 and supports the same plugin interfaces for the subject device Scan&GO mobile workflow and integration of post-processing tasks as the primary predicate device.

V. Indications for Use

NAEOTOM Alpha:

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.

Scan&GO:

This in-room scan application is a planning and information system designed to perform the necessary functions required for planning and controlling scans of supported SIEMENS CT scanners. It allows users to work in close proximity to the scanner.

The in-room scan application runs on standard information technology hardware and software, utilizing the standard information technology operating systems and user interface. Communication and data exchange are done using special protocols.

VI. Comparison of Technological Characteristics with the Predicate Device

The NAEOTOM Alpha scanner provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the primary predicate device.

The subject device NAEOTOM Alpha is building on the dual-source CT system configuration of the primary predicate device NAEOTOM Alpha with software version SOMARIS/10 *syngo* CT VA40.

The predicate device and the subject device NAEOTOM Alpha features two photon counting detectors built from Cadmium-Telluride (CdTe).

Supported by the subject device, SOMARIS/10 *syngo* CT VA50 software version is a further development of the SOMARIS/10 *syngo* CT VA40 software version which is cleared in K211591.

It reuses all unmodified software features of the legacy software *syngo* CT VA40 as described below in the section "Unmodified Features used in the Subject Devices".

The NAEOTOM Alpha with *syngo* CT VA50 also supports an optional laser component for a modified CT guided intervention workflow.

As with the primary device NAEOTOM Alpha with *syngo* CT VA40, the subject device NAEOTOM Alpha is supported by an optional mobile workflow, Scan&GO.

Software version SOMARIS/10 *syngo* CT VA50 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 remains unchanged from the cleared primary predicate device.

At a high level, the subject device NAEOTOM Alpha and the primary/secondary predicate device 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
- Tin filtration technology
- Vectron X-ray Tube
- Power Generator
- Mobile Medical application Software functionality (Scan&GO)
- Mobile workflow (Tablet)
- Support 3D Camera operation for fast patient positioning workflow
- Scanner display and control functionality
- Remote Scan Control
- Long scan range

The following technological differences exist between the subject device NAEOTOM Alpha and the primary predicate device NAEOTOM Alpha with *syngo* CT VA40 cleared in K211591:

- Software version SOMARIS/10 *syngo* CT VA50
- CT guided intervention – modified hardware and software application

The following technological differences exist between the subject device Scan&GO mobile application software and the predicate device Scan&GO mobile application software cleared in K211591:

- Software version SOMARIS/10 *syngo* CT VA50
- CT guided intervention – modified hardware and software application

The NAEOTOM Alpha will support the following modifications/further developments in comparison to the primary/secondary predicate devices as listed in the tables below.

1) New/Modified Hardware
    - **Table 1**: Overview of hardware modifications
2) Software version SOMARIS/10 *syngo* CT VA50
    - **Table 2**: Overview of software modifications

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

Table 1: Overview of term definition.

Term	Definition
N/A	The feature is not supported for the subject device
New	The feature is newly supported for Siemens CT Scanners and the subject device
Modified	This feature is modified from the predicate / reference 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 VA50 and is substantially equivalent compared to the cleared version.

New/modified hardware features:

Table 2: Overview of hardware modifications of NAEOTOM Alpha supported by software version SOMARIS/10 syngo CT VA50.

	Hardware properties	Subject device **NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50
1.	CT guided intervention – MyNeedle Laser	enabled
2.	Tablet dock for patient table	enabled
3.	Interventional Joystick (IVJ)	enabled
4.	Integrated Injector Arm	enabled
5.	Tablet hardware for Scan&GO	modified

New/modified software features:

Table 3: Overview of software modifications of NAEOTOM Alpha supported by software version SOMARIS/10 syngo CT VA50.

	Software properties	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (subject device)
1.	CT guided intervention – MyNeedle Guide	enabled
2.	Flex 4D Spiral – Neuro & Body Perfusion/ Dynamic Angio	modified
3.	Quantum 70 kV	modified
4.	QuantumPlus UHR	modified
5.	Flash Phase Spiral	modified
6.	PURE Calcium	new
7.	Iterative Metal Artifact Reduction (iMAR)	enabled
8.	Automated Patient Instructions	modified
9.	QuantumPlus Topo (Spectral Topo)	modified
10.	Multi-Threshold Acquisition	modified
11.	High Resolution Dual Source Cardiac Modes	modified
12.	Additional ex-factory exam protocols	modified

A tabular summary of the comparable hardware and software properties between the subject device NAEOTOM Alpha with software version *syngo* CT VA50 and primary/secondary predicate device are listed in Table 4 and Table 5 below (modifications are in gray shaded sections).

Table 4: Technical hardware characteristics for subject device NAEOTOM Alpha (software version SOMARIS/10 syngo CT VA50) compared to the predicate devices.

Hardware property	**Subject device**	**Primary predicate device**	**Secondary predicate device**
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VA50	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA40 (K211591)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VA40 (K211373)
Scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner
Scan Mode	Dual Source Dual Energy	Dual Source Dual Energy	Single Source Dual Energy

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VA50	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA40 (K211591)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VA40 (K211373)
Generator max. power	2x 120 kW	2x 120 kW	105 kW/ 120 kW
Detector Technology	QuantaMax Direct Conversion with "Quantum Technology"	QuantaMax Direct Conversion with "Quantum Technology"	Stellar^{infinity} Energy integrating
Detector volume coverage	2 x 57.6 mm	2 x 57.6 mm	38.4 mm
Detector physical rows	2x 288	2x 288	64
Detector slice width	0.2 mm	0.2 mm	0.6 mm
Detector channel No.	2752 (A system) 1984 (B system)	2752 (A system) 1984 (B system)	920
X-ray Tube	VECTRON	VECTRON	VECTRON
Tube kV steps	70 kV, 90 kV, 100 kV, 120 kV, 140 kV	90 kV, 100 kV, 120 kV, 140 kV	70 kV to 150 kV (in 10 kV steps)
Tube max. current	2 x 1300 mA	2 x 1300 mA	1200 mA; for 105 kW 1300 mA; for 120 kW
Tube tube focus	0.4 mm x 0.5 mm 0.6 mm x 0.7 mm 0.8 mm x 1.1 mm (for both tubes)	0.4 mm x 0.5 mm 0.6 mm x 0.7 mm 0.8 mm x 1.1 mm (for both tubes)	min. 0.6 mm x 0,7 mm (w/o comb) min. 0.4 mm x 0.5 mm (with comb)
Tube heat capacity	higher than 30 MHU	higher than 30 MHU	higher than 30 MHU
Gantry bore size	82 cm	82 cm	82 cm
Gantry Scan FoV	50 cm	50 cm	50 cm
Gantry rotation time [s]	0.25 s, 0.5 s, 1.0 s	0.25 s, 0.5 s, 1.0 s	0.25 s, 0.3 s, 0.5 s, 1.0 s
Gantry Tilt [degree]	N/A	N/A	+/- 25 +/- 30 (only with Vitus)

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VA50	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA40 (K211591)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VA40 (K211373)
Patient Table type	Vario 2.D Vitus	Vario 2.D Vitus	Vario 2.D Vitus Vario RT
Max. Scan length Topogram	Vario 2.D: 2080 mm Vitus: 2080 mm	Vario 2.D: 2080 mm Vitus: 2080 mm	Vario 2.D: 2080 mm Vitus: 2080 mm Vario RT: 1680 mm
Max. Scan length Image acquisition	Vario 2.D: 2000 mm Vitus: 2000 mm	Vario 2.D: 2000 mm Vitus: 2000 mm	Vario 2.D: 2000 mm Vitus: 2000 mm Vario RT: 1600 mm
Spectral filtration Option*	Tin Filter for both tubes	Tin Filter for both tubes	Combined Split Filter / Tin Filter supported, plus extra Tin Filter
3D Camera for patient positioning	option for patient positioning with 3D Camera	option for patient positioning with 3D Camera	option for patient positioning with 3D Camera
Tablet dock for patient table	Option for mounting of the tablet on the patient table.	N/A	Option for mounting of the tablet on the patient table.
Interventional Joystick (IVJ)	Option to support the tablet mobile workflow including an electrical connection for the tablet dock which allows charging the tablet when mounted.	N/A	Option to support the tablet mobile workflow including an 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	N/A	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions

Table 5: Software characteristics for subject device NAEOTOM Alpha (software version SOMARIS/10 syngo CT VA50) compared to the predicate devices.

Software property	**Subject device**	**Primary predicate device**	**Secondary predicate device**
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VA50	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA40 (K211591)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VA40 (K211373)
Operating System	Windows based SOMARIS/10 *syngo* CT VA50	Windows based SOMARIS/10 *syngo* CT VA40	Windows based SOMARIS/10 *syngo* CT VA40
Acquisition Workplace	*syngo* Acquisition Workplace named as "myExam Console" *syngo* Viewing, *syngo* Filming and *syngo* Archiving & Networking 2nd Acquisition Workplace named as "myExam Satellite"	*syngo* Acquisition Workplace named as "myExam Console" *syngo* Viewing, *syngo* Filming and *syngo* Archiving & Networking 2nd Acquisition Workplace named as "myExam Satellite"	*syngo* Acquisition Workplace named as "myExam Console" *syngo* Viewing, *syngo* Filming and *syngo* Archiving & Networking 2nd Acquisition Workplace named as "myExam Satellite"
IRS	Image Reconstruction for Quantum Technology	Image Reconstruction for Quantum Technology	Image Reconstruction for classic Siemens single source CT scanner
Detector	QuantaMax detector firmware supported	QuantaMax detector firmware supported	Stellar detector firmware supported
Teamplay	Support teamplay Protocols	Support teamplay Protocols	Support 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 • Dynamic imaging (Flex 4D Spiral)	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 Cardiac Scanning, Spectral imaging for	• Protocols for Radiation Therapy Planning support patient marking • Protocols that allow scanning with support of an external respiratory gating system (ANZAI, Varian RGSC) • Protocol supporting contrast bolus-triggered data acquisition

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VA50	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA40 (K211591)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VA40 (K211373)
	• various i-spiral scan protocols and FAST i-sequence (applying different scanning parameters such as different slice thicknesses, kV settings or reconstructions kernels to support different clinical scenarios) and using features like iMAR, CARE Dose4D and CARE kV • Protocols supporting Intervention, Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution	child examination, Spectral imaging with high resolution	• Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • TwinBeam DE • TwinSpiral DE • Dynamic imaging (Flex 4D Spiral) • various i-spiral scan protocols and FAST i-sequence (applying different scanning parameters such as different slice thicknesses, kV settings or reconstructions kernels to support different clinical scenarios) and using features like iMAR, CARE Dose4D and CARE kV • Protocols supporting Intervention
Advanced Reconstruction	Recon&GO: - Spectral Recon (Dual Energy Reconstruction from photon counting data) / including Virtual Unenhanced, Monoenergetic plus - Inline Results DE SPP (Spectral Post-Processing with photon counting image data)	Recon&GO: - Spectral Recon (Dual Energy Reconstruction from photon counting data) / including Virtual Unenhanced, Monoenergetic plus - Inline Results DE SPP (Spectral Post-Processing with photon counting image data)	Recon&GO: - Spectral Recon (Dual Energy Reconstruction) - Inline Results DE SPP (Spectral Post-Processing) / including Virtual Unenhanced, Monoenergetic plus
Post- Processing Interface	• Recon&GO Inline Results:	• Recon&GO Inline Results:	• Recon&GO Inline Results:

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VA50	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA40 (K211591)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VA40 (K211373)
	Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices in their own right. • software interfaces for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone Advanced Visualization Application software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners. Additional information regarding the points of interface and inputs for this feature is provided in Section 16.	Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices in their own right. • software interfaces for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone Advanced Visualization Application software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners. Additional information regarding the points of interface and inputs for this feature is provided in Section 16.	Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices in their own right. • software interfaces for post-processing functionalities to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. Note: The clearance of standalone Advanced Visualization Application software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners. Additional information regarding the points of interface and inputs for this feature is provided in Section 16.
Cybersecurity	IT Hardening	IT Hardening	IT Hardening

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VA50	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA40 (K211591)	**SOMATOM X.ceed** SOMARIS/10 *syngo* CT VA40 (K211373)
Standard technologies	• FAST Features • CARE Features • GO technology • CARE keV	• FAST Features • CARE Features • GO technology • CARE keV	• FAST Features • CARE Features • GO technology • CARE kV
Iterative Reconstruction Methods	Quantum Iterative Reconstruction iMAR	Quantum Iterative Reconstruction	ADMIRE iMAR
Precision Matrix	Precision Matrix resolution support image matrix sizes of 512x512, 768x768 pixels and 1024x1024 pixel (auto mode supported)	Precision Matrix resolution support image matrix sizes of 512x512, 768x768 pixels and 1024x1024 pixel (auto mode supported)	image matrix sizes 256x256, 512x512 and 768x768 pixels
CaScoring	Photon counting technology offers monoenergetic images which can be used as a base for calcium scoring independent from tube voltage kV and beam filtration settings.	Photon counting technology offers monoenergetic images which can be used as a base for calcium scoring independent from tube voltage kV and beam filtration settings.	Classic SOMATOM X.ceed technology offers images which can be used for calcium scoring, independent from tube voltage kV and beam filtration settings based on a dedicated single energy image reconstruction method.

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation is completed. Test results show that the subject device, the NAEOTOM Alpha with *syngo* CT VA50, is comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

VII. Performance Data

Non-Clinical Testing

Non-clinical testing, (integration and functional) including phantom tests were conducted for the NAEOTOM Alpha 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 covered 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

Feature/Non-clinical supportive testing	**Testing performed**
myNeedle Laser	The performed bench test covers the laser accuracy evaluation. The results of the accuracy test with a close to clinical workflow and test setup show that defined accuracy level can be achieved.
myNeedle Laser	The performed bench test report covers the workflow evaluation. A comparison to the essential workflow steps is performed.
Flex 4D Spiral – Neuro & Body Perfusion/ Dynamic Angio	The performed bench test describes the technical background of Flex 4D Spiral and added functionalities with NAEOTOM Alpha (dynamic collimation and dose modulation), demonstrates the proper function of those and assesses the image quality of Flex 4D Spiral on NAEOTOM Alpha at all.
QuantumPlus UHR	The performed bench test describes the reconstruction of spectral images from raw data acquired in ultra-high resolution (UHR) modes.
PURE Calcium	The performed bench test describes the feature “PURE Calcium”, which uses spectrally acquired input image data generated by the subject device NAEOTOM Alpha to obtain a modified image

Feature/Non-clinical supportive testing	Testing performed
	reconstruction that aims at removing the iodine contribution from the generated output images.
Iterative Metal Artifact Reduction (iMAR)	The performed bench test covers evaluation of phantom images to demonstrate the efficacy of iMAR to reduce metal arti-facts.
High Resolution Dual Source Cardiac Modes	The performed bench test describes the basic image quality and the property of the ECG gated ultra-high resolution dual source cardiac acquisition mode introduced in NAEOTOM Alpha with software version *syngo* CT VA50.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the subject device NAEOTOM Alpha in accordance with the following standards: 60601-2-44, and 60601-1-2. 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 Recognition	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
06/27/2016	12-300	NEMA	PS 3.1 - 3.20 (2016)	Digital Imaging and Communications in Medicine (DICOM) Set
07/06/2020	12-325	NEMA	XR 25-2019	Computed Tomography Dose Check
01/27/2015	12-287	NEMA	XR 28-2013	Supplemental Requirements for User Information and System Function Related to Dose in CT
06/27/2016	5-40	ANSI AAMI ISO	14971:2007/(R)2010 (Corrected 4 October 2007)	Medical Devices - Applications Of Risk Management To Medical Devices
		ISO	14971 Second edition 2007-03-01	Medical Devices - Applications Of Risk Management To Medical Devices
01/14/2019	13-79	IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical Device Software - Software Life Cycle Processes
07/09/2014	19-4	ANSI AAMI	ES60601-1:2005/(R)2012 And A1:2012,	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential

Date of Recognition	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				performance (IEC 60601-1:2005, MOD)
09/17/2018	19-8	ANSI AAMI IEC	60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
12/23/2016	5-114	ANSI AAMI IEC	62366-1:2015	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 [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)] Note: Requirements according to IEC 60825-1:2014 (Ed.3.0) are implemented.
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
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
06/27/2016	5-89	IEC	60601-1-6 Edition 3.1 2013-10	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
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

Date of Recognition	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				performance of computed tomography X-ray equipment
01/30/2014	12-270	IEC	61223-3-5 First Edition 2004-08	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
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 - Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
06/07/2018	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
06/27/2016	12-299	IEC	62563-1 Edition 1.1	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	Medical electrical equipment - part 1: general requirements for basic safety and essential performance	Covered by ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 as part of EMC testing.
IEC/ISO	17050-1	Conformity Assessment – Supplier's declaration of conformity – Part 1: General requirements	Declaration of conformance to FDA recognized consensus standards.

Standard Developing Organization	Standard Designation Number and Date	Title of Standard	How was Standard Used
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 and Effective Date
1.	Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k)** Document issued on October 2, 2017
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s** Document issued on February 21, 2019
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff** Document issued on August 12, 2005
4.	Guidance for Industry and FDA Staff: **Deciding when to submit a 510(k) for a change to an existing device.** Document issued on October 25, 2017
5.	Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** Document Issued on July 28, 2014
6.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices** Document issued on May 11, 2005
7.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices** Document issued on September 9, 1999
8.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability** **Engineering to Medical Devices**. Document issued February 3, 2016
9.	Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging** **Device Premarket Notifications.**

	Document issued on November 28, 2017
10.	Guidance for Industry and FDA Staff: **Content of Premarket Submissions for Management of Cybersecurity in Medical devices.** Document issued on October 2, 2014
11.	Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices** Document issued on July 11, 2016
12.	Guidance for Industry and Food Drug Administration Staff: **Design considerations and Pre-Market Submission recommendations for Interoperable Medical devices** Document Issued on September 6, 2017
13.	Guidance for Industry and Food Drug Administration Staff: **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices** Document issued on September 14, 2018

Verification and Validation

Software documentation for a moderate level of concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. 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.

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. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014" is included within this submission**.**

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 to IEC60601-2-44.

Wireless Coexistence Testing

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.

VIII. Conclusions

The primary and secondary predicate devices were cleared based on the results of non-clinical testing including verification and validation, phantom tests, and supportive literature. The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrates that the NAEOTOM Alpha should perform as intended in the specified use conditions. The data included in this submission demonstrates that the NAEOTOM Alpha with described modifications performs comparably to the primary predicate device currently marketed for

the same intended use. Siemens believes that the data generated from the NAEOTOM Alpha testing supports a finding of substantial equivalence.