March 28, 2024

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

Re: K233657
Trade/Device Name: NAEOTOM Alpha
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 22, 2024
Received: February 23, 2024

Dear Tabitha Estes:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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.

Submission Number *(if known)*

K233657

Device Name

NAEOTOM Alpha

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 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.

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
with software version SOMARIS/10 *syngo* CT VB10

Date Prepared: March 22, 2024

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 -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:	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

III. Predicate Device

Primary Predicate Device:

Trade Name:	NAEOTOM Alpha, Scan&GO
510(k) Number:	K220814
Clearance Date:	July 12, 2022
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 Force
510(k) Number:	K230421
Clearance Date:	June 16, 2023
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: K230421 was a bundle submission with various Siemens CT Scanner Systems, including the dual source CT scanner systems SOMATOM Drive, SOMATOM Force, SOMATOM Definition Flash and the single source CT scanner CT systems SOMATOM Edge Plus, SOMATOM Confidence, SOMATOM Definition Edge, SOMATOM Definition AS/AS+, SOMATOM Definition AS Open.

IV. Device Description

Siemens intends to market a new software version, SOMARIS/10 *syngo* CT VB10, for the Dual Source CT system NAEOTOM Alpha based on the SOMARIS/10 platform.

The subject device NAEOTOM Alpha with software version SOMARIS/10 *syngo* CT VB10 is a Computed Tomography X-ray system which features two continuously rotating tube-detector systems, denominated as A- and B-systems respectively (dual source CT scanner system). The detectors' function is based on photon-counting technology. The NAEOTOM Alpha with SOMARIS/10 *syngo* CT VB10 produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens 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.

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 is *syngo* CT VB10 (SOMARIS/10 *syngo* CT VB10). It is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The software platform 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 VB10 (SOMARIS/10 *syngo* CT VB10) is a modified software version of the primary predicate device, *syngo* CT VA50 (SOMARIS/10 *syngo* CT VA50) cleared in K220814.

Software version SOMARIS/10 *syngo* CT VB10 will be offered ex-factory and as optional upgrade for the existing NAEOTOM Alpha systems.

The subject device NAEOTOM Alpha will support previously cleared software and hardware features in addition to the applicable modifications as described within this submission. The intended use and the indications for use remain 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 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.

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 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.

Primary Predicate Device Indications for Use:

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

The images delivered by the system can be used by a trained staff as an aid in diagnosis and treatment as well as for diagnostic and therapeutic interventions.

This CT system can be used for low dose lung cancer screening in high risk populations*.

* As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Secondary Device Indications for Use:

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*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:

1. The subject device Indications for Use is the exact same as the primary predicate's Indications for Use (K220814), however it is slightly different than the secondary predicate's Indications for Use.

2. Compared to the secondary predicate device, the subject device does not contain the phrase “radiation therapy planning” in the sentence “The images delivered by the system can be used by a trained staff as an aid in diagnosis and treatment as well as for diagnostic and therapeutic interventions.” because NAEOTOM Alpha does not support radiation therapy planning.

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 NAEOTOM Alpha is not the principal means of guidance, because the CT System does not guide the invasive procedures, the needle orientation and the needle advance, and handling is always done under the physicians control.

VII. Comparison of Technological Characteristics with the Predicate Device

Supported by the subject device, SOMARIS/10 *syngo* CT VB10 software version is a further development of the SOMARIS/10 *syngo* CT VA50 software version which is cleared in K220814.

The NAEOTOM Alpha with SOMARIS/10 *syngo* CT VB10 software version provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software features of NAEOTOM Alpha have been modified or improved in comparison to the predicate devices to support enhanced device functionality compared to the predicate devices.

The new *syngo* CT VB10 software reuses all unmodified software features of the legacy software *syngo* CT VA50 cleared in K220814. Additionally, no features present in the predicate device are descoped.

Software version SOMARIS/10 *syngo* CT VB10 is designed to reuse hardware independent extended functionalities and GO technologies provided by Siemens cleared software applications.

The intended use and fundamental scientific technology for the NAEOTOM Alpha remain unchanged from the predicate devices.

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

- Scanner Principle – Whole body X-Ray Computed Tomography Scanner
- System Acquisition – Continuously rotating tube detector system
- Iterative Reconstruction – Support of various iterative reconstruction principles
- Workplaces – Support of workplaces that include reconstruction and image evaluation software
- Patient table
- Patient table foot switch for movement
- 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 device NAEOTOM Alpha with SOMARIS/10 *syngo* CT VB10 will support the modifications/further developments in comparison to the predicate devices as listed in the tables under subsections 1) Modified Hardware and 2) Modified Software below.

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
New	The feature is newly supported for Siemens CT Scanners and the subject device
Modified	This feature is a modified form of a feature cleared within the predicate devices
Enabled	This feature is currently supported by other cleared Siemens CT systems or cleared Siemens stand-alone software applications.

1) Modified Hardware

Table 2: Overview of hardware modifications of NAEOTOM Alpha supported by software version SOMARIS/10 syngo CT VB10 compared to the predicate/secondary devices.

	Hardware properties	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (subject device)
1.	Tin Filtration	modified
2.	FAST 3D Camera	modified
3.	Multi-Purpose Table (Vitus)	modified

2) Modified Software (*syngo* CT VB10)

Table 3: Overview of software modifications of NAEOTOM Alpha supported by software version SOMARIS/10 syngo CT VB10 compared to the predicate/secondary devices.

	Software properties	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VB10 (subject device)
1.	ZeeFree	new
2.	FAST Integrated Workflow	modified
3.	myNeedle Guide (with MyNeedle Detection)	modified
4.	myExam Companion – myExam Cockpit/myExam Compass	modified
5.	Recon&GO	modified

	Software properties	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10 (subject device)
6.	CT View&GO	modified
7.	Scan&GO	enabled
8.	Quantum Spectral Imaging	modified
9.	Quantum HD Cardiac	modified
10.	HD FoV	enabled
11.	Multi-Threshold Acquisition	modified
12.	myExam Satellite (Remote Recon)	modified

A tabular summary of the comparable hardware and software properties between the subject device NAEOTOM Alpha with software version *syngo* CT VB10 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 the subject device NAEOTOM Alpha (software version SOMARIS/10 syngo CT VB10) compared to the predicate devices.

Hardware property	**Subject device**	**Primary predicate device**	**Secondary predicate device**
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
Scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner
System configuration	Dual Source	Dual Source	Dual Source
Environment of Use	Professional Healthcare Facility	Professional Healthcare Facility	Professional Healthcare Facility
Generator max. power (kW)	2x 120	2x 120	2x 120
Detector technology	QuantaMax	QuantaMax	UFC (Ultra Fast Ceramic)

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	Direct Conversion with "Quantum Technology"	Direct Conversion with "Quantum Technology"	
Detector volume coverage (mm)	2x 57.6	2x 57.6	2x 57.6
Detector physical rows	2x 288	2x 288	2x 96
Detector slice width (mm)	0.2	0.2	0.6 (optional: 0.4, 0.5)
Detector DAS channel no.	2752 (A system) 1984 (B system)	2752 (A system) 1984 (B system)	920 (A system) 640 (B system)
Tube technology	VECTRON	VECTRON	VECTRON
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	70, 80, 90, 100, 110, 120, 130, 140, 150
Tube max. current (mA)	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°	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°

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	(for both tubes)	(for both tubes)	(for both tubes)
Tube heat capacity	higher than 30 MHU	higher than 30 MHU	Higher than 30 MHU
Gantry bore size (cm)	82	82	78
Gantry Scan FoV (cm)	50	50	50
Gantry rotation time (sec)	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.25*, 0.285, 0.325*, 0.5, 1.0 (*optional)
Gantry Tilt (degree)	N/A	N/A	N/A
Maximum temporal resolution in ECG gated or triggered examination (ms)	mono-segment: 66 bi-segment: 33	mono-segment: 66 bi-segment: 33	mono-segment, standard: 75 mono-segment, optional: 66 bi-segment, standard: 38 bi-segment, optional: 33
Maximum scan speed at pitch (mm/s at pitch x)	737 mm/s at pitch 3.2	737 mm/s at pitch 3.2	737 mm/s at pitch 3.2
Patient Table Type	Vario 2.D Vitus	Vario 2.D Vitus	PHS5 MPT4
Max. Scan length Topogram (mm)	Vario 2.D: 2080 Vitus: 2080	Vario 2.D: 2080 Vitus: 2080	PHS5: 1970 MPT4: 1970
Max. Scan length	Vario 2.D: 2000	Vario 2.D: 2000	PHS5: 1953

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
Image acquisition (mm)	Vitus: 2000	Vitus: 2000	MPT4: 1953
Patient table Max. weight capacity (kg)	Vario 2.D: 307 Vitus: 307 or 340	Vario 2.D: 307 Vitus: 307	PHS5: 227 MPT4: 227 or 307 (with bariatric/trauma table top)
Patient table Installation option	Regular installation (Vario 2.D and Vitus): 474 mm Installation option with extended distance (Vitus): 674 mm (474 mm + 200 mm)	Regular installation (Vario 2.D and Vitus): 474 mm	Regular installation (PHS5 and MPT4): 400 mm
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	Tin Filter for both tubes: 0.6 mm
FAST 3D Camera for patient positioning	option for patient positioning with 3D Camera ceiling mounted, modified design	option for patient positioning with 3D Camera ceiling mounted	option for patient positioning with 3D Camera ceiling mounted
X-ray foot switch	Option to trigger hands-free scanning	Option to trigger hands-free scanning	Option to trigger hands-free scanning

Hardware property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
Table foot switch	Option for table patient movement	Option for table patient movement	N/A
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.	N/A
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.	i-control: option to operate some of the CT functions including patient table movement as an alternative to the gantry operating panel and the input units at the console.
Laser supported workflow	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position; myNeedle Laser visualizes a planned needle path for interventions	Laser in combination with FAST Isocentering visualize coordinates for patient isocenter position;

Table 5: Software characteristics for the subject device NAEOTOM Alpha (software version SOMARIS/10 syngo CT VB10) compared to the predicate devices.

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
Operating System	Windows based SOMARIS/10 *syngo* CT VB10 Note: the short version *syngo* CT VB10 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VA50 Note: the short version *syngo* CT VA50 is also used as labeling information	Windows based SOMARIS/7 *syngo* CT VB30 Note: the short version *syngo* CT VB30 is also used as labeling information
Workplace	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as "myExam Satellite" with Remote Recon function	*syngo* Acquisition Workplace (ICS) named as "myExam Console" Image Reconstruction for Quantum Technology (IRS) 2nd workplace option named as "myExam Satellite"	*syngo* Acquisition Workplace (AWP) Optional second operating system (Remote Recon Workplace, RRWP)
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
Detector firmware	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	Support of: • Protocol supporting contrast bolus-triggered data acquisition	Support of: • Protocols supporting contrast bolus-triggered data acquisition

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	• Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition • Dynamic imaging (Flex 4D Spiral) • Protocols supporting CT Intervention, Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum HD (previously: Quantum High resolution) - Quantum HD Cardiac (previously High resolution Dual Source Cardiac modes). In addition, a spectral image results from dual source 96x0.2mm ultra high-resolution mode can optionally be obtained	• Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition • Dynamic imaging (Flex 4D Spiral) • Protocols supporting CT Intervention, Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution • Protocols for Quantum Imaging modes: - Quantum - Quantumplus - Quantum High resolution - High resolution Dual Source Cardiac modes	• Contrast media protocols (including coronary CTA) • Pediatric Protocols • Turbo Flash Spiral • Dual Source Dual Energy protocols • Adaptive 4D Spiral • Protocols for Radiation Therapy Planning • Dual Source Dual Energy protocols for Radiation Therapy Planning • Protocols for CT intervention, Cardiac Scanning

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	- Quantumpeak (Quantumpeak mode is identical to the Dual Source Dual Energy modes at SOMATOM Dual Source Scanners in K230421		
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) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus (already cleared with the stand-alone medical device *syngo*.via (K191040) - Inline Spine and Rib Ranges (already cleared with the stand-alone medical device *syngo*.CT Applications (syngo.CT Bone Reading) K220450))	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)	Advanced reconstruction tools supported: The *syngo* acquisition workplace provides image reconstruction and routine postprocessing.

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	- Inline table and bone removal (already cleared with the stand-alone medical device *syngo*.CT Extended Functionality (K221727))		
Image viewing	CT View&GO offers: - basic post-processing viewer (CT View&GO) - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI) - Basic visualization tools: Endoscopic View - Basic manipulation tools: DE ROI, ROI HU Threshold, Average - Automated table and bone removal (already cleared with the stand-alone medical device *syngo*.CT Extended Functionality (K221727))	CT View&GO offers: - basic post-processing viewer (CT View&GO) - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing	*syngo* Viewing offers: - 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing
Post-Processing interface	• Recon&GO Inline Results: Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k)	• Recon&GO Inline Results: Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k)	syngo.via - Wide Range of individual applications, syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	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.	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.	images. It can be used as a standalone device or together with a variety of cleared and unmodified syngo based software options.
Cybersecurity	IT Hardening	IT Hardening	IT Hardening
HD FoV	supported	N/A	supported

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
Standard technologies	• FAST technologies • CARE technologies • GO technologies • CARE keV	• FAST technologies • CARE technologies • GO technologies • CARE keV	• FAST technologies • CARE technologies
myExam Companion – myExam Compass/myExam Cockpit	• myExam Compass collects information about the current patient to dynamically adapt the scan parameters or exchange recon jobs according to the patient's characteristics • myExam Cockpit option of displaying, modifying, creating, and deleting Clinical Decision Trees (CDTs). myExam Compass functionality offers the possibility to activate/deactivate diagnostic scan ranges, Bolus Tracking and Test Bolus ranges. myExam Cockpit allows to define these new settings.	• myExam Compass collects information about the current patient to dynamically adapt the scan parameters or exchange recon jobs according to the patient's characteristics • myExam Cockpit option of displaying, modifying, creating, and deleting Clinical Decision Trees (CDTs).	N/A
Scan&GO	Scan&GO With software version *syngo* CT VB10, the previously stand-alone Scan&GO software functionality is fully incorporated into the subject device CT scanner system. The	Scan&GO	N/A

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	functionality remains unchanged.		
Reconstruction Options for Cardiac Imaging	• Standard (renamed from "TrueStack 'off'" on the primary predicate device) • TrueStack (renamed from "TrueStack 'on'" on the primary predicate device) • ZeeFree allows the reconstruction of ECG-gated spiral or ECG-triggered sequence data in a cardiac cycle-to-cycle border aligned fashion	• TrueStack "off" • TrueStack "on"	• TrueStack "off" • TrueStack "on"
Iterative Reconstruction Methods	Quantum Iterative Reconstruction iMAR	Quantum Iterative Reconstruction iMAR	ADMIRE SAFIRE iMAR
Precision Matrix	Precision Matrix resolution support image matrix sizes of: 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels	Precision Matrix resolution support image matrix sizes of: 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels	Precision Matrix resolution support image matrix sizes of: 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels
Multi-Threshold Acquisition			N/A

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	• acquisition, storage, and reconstruction of projection raw data of different energy thresholds (T1, T2, T3 and T4) • projection raw data of the three higher energy thresholds (T2, T3, and T3) can be reconstructed by offline reconstruction tools or on the CT system	• acquisition, storage, and reconstruction of projection raw data of different energy thresholds (T1, T2, T3 and T4) • projection raw data of the three higher energy thresholds (T2, T3, and T3) are reconstructed by offline reconstruction tools.	
myNeedle Guide	• plan the needle path and perform control scans (i-Sequence, i-Spiral, i-Fluoro) • myNeedle Detection algorithm (modification of the myNeedle Guide 3D software)	• plan the needle path and perform control scans (i-Sequence, i-Spiral, i-Fluoro)	N/A
FAST 3D Camera with FAST Integrated Workflow	FAST Integrated Workflow including the sub-features FAST Range, FAST Isocentering and FAST Direction FAST Range, FAST Isocentering and FAST Direction algorithms optimized with data	FAST Integrated Workflow including the sub-features FAST Range, FAST Isocentering and FAST Direction	FAST Integrated Workflow including the sub-features FAST Range, FAST Isocentering and FAST Direction

Software property	Subject device	Primary predicate device	Secondary predicate device
	NAEOTOM Alpha SOMARIS/10 *syngo* CT VB10	**NAEOTOM Alpha** SOMARIS/10 *syngo* CT VA50 (K220814)	**SOMATOM Force** SOMARIS/7 *syngo* CT VB30 (K230421)
	from the redesigned camera.		

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 VB10, is comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

VIII. Performance Data

Non-Clinical Testing

Non-clinical testing, (integration and functional) including phantom tests were conducted for the 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 will cover all related subsystems that contribute to the device modifications. Test levels are defined. For each test level several test activities are performed. The test specification and acceptance criteria are related to the corresponding requirements. Various test activities are performed to specific modifications on different test levels to ensure safe and effective integration in the system. Three test levels are defined:

System Validation test:

- Acceptance test (workflow and user manual test)
- Legal and Regulatory test

System Verification test:

- System Integration Test (functional)
- Functionality verification
- Image Quality (IQ) Evaluation

Tests are conducted for all software components developed in product development and for the complete product itself. Several activities are considered for this process, including creation of test specifications that relate to software/hardware requirements including tests to address risk mitigations that are identified, documented, and traced by hazard keys.

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

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

Feature/Non-clinical supportive testing	**Bench Testing performed**
FAST 3D Camera / FAST Integrated Workflow	The bench test evaluates and compares the accuracy of the three sub-features FAST Isocentering, FAST Range, and FAST Direction to the accuracy of the predicate device with *syngo* CT VA50 using the old camera hardware and the then only available ceiling mount. The objectives of the bench test are to demonstrate that the FAST 3D Camera feature of the subject device with SOMARIS/10 *syngo* CT VB10, where the algorithms have been optimized for a new camera hardware in two mounting positions, achieves comparable results as the predicate device with *syngo* CT VA50. The FAST Isocentering accuracy of the subject device with *syngo* CT VB10 is comparable to the predicate device with syngo CT VA50, regardless of the camera mounting position. For the FAST Range feature, the detection accuracy of all body region boundaries is comparable between the subject device with *syngo* CT VB10 and predicate device with *syngo* CT VA50. The FAST Direction pose detection results are of comparable accuracy for subject and predicate device, regardless of the camera mounting position. Overall, the SOMARIS/10 *syngo* CT VB10 delivers comparable accuracy to the SOMARIS/10 *syngo* CT VA50 predicate for the new FAST 3D Camera hardware.
Multi-Purpose Table	This document describes a hardware test in which a CT system with extended distance between CT gantry and patient table base plus a mobile C-arm system were combined to evaluate the technical feasibility and possible limitations of this combination. The range of possible movement for the mobile C-arm in different positions between CT gantry and patient table was tested and documented by measurement of angles. Based on the test results it can be concluded that a CT scanner, equipped with a Multi-Purpose (Vitus) Patient Table, which is installed with enhanced distance (674 mm) to the CT gantry and offers the iCT mode functionality, provides sufficient freedom of movement for a mobile C-arm X-ray system to be used for clinical routine without any significant limitations for my needle Laser or 3D Camera.
ZeeFree	The bench tests evaluate the performance of ZeeFree reconstruction. The objectives of the tests are to demonstrate: • that the number of artefacts which can be attributed to a stack misalignment (e.g. discontinuities in vessel structures, anatomical steps at air-soft-tissue interfaces, doubling of vessel

Feature/Non-clinical supportive testing	Bench Testing performed
	or other anatomy) and which are often caused by incomplete patient breath-hold can be reduced in a “Cardiac Stack Artefact Correction” (SAC) reconstruction compared to the standard reconstruction with otherwise matching reconstruction parameters. • that no artefacts are introduced by a SAC reconstruction. The test results show: • If misalignment artefacts are identified in non-corrected standard ECG-gated reconstructed sequence or spiral images, the feature “Cardiac Stack Artefact Correction” (SAC, marketing name: ZeeFree) enables optional stack artefact corrected images, which reduce the number of alignment artefacts. • The SAC reconstruction does not introduce new artefacts, which were previously not present in the non-corrected standard reconstruction. • The SAC reconstruction does realize equivalent image quality in quantitative standard physics phantom-based measurements (ACR, Gammex phantom) in terms of noise, homogeneity, high-contrast resolution, slice thickness and CNR compared to a non-corrected standard reconstruction. • The SAC reconstruction does realize equivalent image quality in quantitative and qualitative phantom-based measurements with respect to metal objects compared to a non-corrected standard reconstruction. • The SAC algorithm can be successfully applied to phantom data if derived from a suitable motion phantom demonstrating its correct technical function on the tested device. • The SAC algorithm is independent from the physical detector width of the acquired data
myNeedle Guide (with myNeedle Detection)	Tests were performed to ensure clinical usability of the myNeedle Guide needle detection algorithm. Two individual tests were performed. The accuracy of the automatic needle detection algorithm was tested. The reduction of necessary user interactions for navigating to a needle-oriented view with and without the support of the automatic needle detection algorithm was analyzed. It has been shown that the algorithm was able to consistently detect needle-tips over a wide variety of scans in 90.76% of cases. Further, the results of this bench test clearly shows that the auto needle detection functionality reduces the number of interactions steps needed to generate a needle-aligned view in the CT Intervention SW. Zero user interactions are required and a needle-aligned view is displayed right away after a new scan, if auto needle detection is switched on in the SW

Feature/Non-clinical supportive testing	Bench Testing performed
	configuration. Therefore, the test is already passed if only a single user interaction is necessary to achieve a needle-oriented view in the manual workflow.
Quantum Spectral Imaging	Tests were performed to demonstrate that: • T3D reconstructions in Quantumpeak mode are possible with the sharpest available kernels up to Qr89, Br98, etc. • Quantumpeak scan mode allows reconstructions of monoenergetic images at energy levels from 40 to 190 keV. The evaluation has been performed based on phantom studies. The results showed that: • with T3D reconstructions from Quantumpeak scan modes, high resolution images with sharp kernel up to Br98 are obtained. The resolution is comparable to other Highresultra scan modes of the NAEOTOM Alpha. • Monoenergetic reconstructions from Quantumpeak scan modes are free of artifacts. Measured CT values precisely match the reference values. • The accuracy of monoenergetic reconstructions in iodine and calcium inserts at the NAEOTOM Alpha is comparable or better than on the secondary predicate device SOMATOM Force.
Quantum HD Cardiac	Quantitative assessment in terms of image noise and a visual assessment of the image quality in ECG gated acquisitions between different scan modes is performed: standard acquisition mode with spectral and non-spectral reconstruction, ultra-high resolution acquisition mode with non-spectral reconstruction (120x0.2 mm and 96x0.2 mm) and spectral image reconstruction (limited to 96x0.2 mm). Based on the results it can be concluded that substantial equivalence in image quality is achieved by the images derived from the spectral capable cardiac acquisition mode 96x0.2mm for both, the high-resolution UHR and the standard resolution spectral image cases, compared to the single source spectral capable 120x0.2mm UHR scan mode.
HD FoV	Tests were performed to evaluate the performance of HD FoV on NAEOTOM Alpha. For this purpose, the HU accuracy in the extended field of view region was measured based on phantom studies. The phantom diameter accuracy has been also evaluated. Based on the results it can be concluded that HD FoV enables the reconstruction of images while significantly improving the visualization

Feature/Non-clinical supportive testing	Bench Testing performed
	of anatomy in the regions outside the scan field of view of 50 cm. In the phantom study, an HU value accuracy of about ± 40 HU was achieved with skin-line accuracy of about ± 3 mm.

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

Table 7: Recognized Consensus Standards.

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
12/19/2022	12-349	NEMA	PS 3.1 - 3.20 2022d	Digital Imaging and Communications in Medicine (DICOM) Set
07/06/2020	12-325	NEMA	XR 25-2019	Computed Tomography Dose Check
07/06/2020	12-330	NEMA	XR 28-2018	Supplemental Requirements for User Information and System Function Related to Dose in CT
12/23/2019	12-328	IEC	61223-3-5 Edition 2.0 2019-09	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests and constancy tests - Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
03/14/2011	12-226	IEC	61223-2-6 Second Edition 2006-11	Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
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	12-302	IEC	60601-2-44 Edition 3.2: 2016	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
12/23/2019	5-125	ANSI AAMI ISO	14971: 2019	Medical devices - Applications of risk management to medical devices
		ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
01/14/2019	13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
		IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
07/09/2014	19-46	ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

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

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

FDA Guidance Document	Issue date
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 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 device and the hardware and software verification and validation demonstrates that the NAEOTOM Alpha performs 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 with described modifications performs comparably to the predicate devices currently marketed for the same intended use. The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices.