September 30, 2021

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

Re: K211591
Trade/Device Name: NAEOTOM Alpha, Scan&GO
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 19, 2021
Received: August 20, 2021

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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K211591

Device Name
NAEOTOM Alpha
Scan&GO

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 physician as an aid in diagnosis.
The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

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 AND SCAN&GO

Submitted by:
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
Knoxville, TN 37932
Date Prepared: February 21, 2021

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.
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Knoxville, TN 37932
Establishment Registration Number
1034973

Importer/Distributor
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Establishment Registration Number
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Location of Manufacturing Site (1)
Siemens Healthcare GmbH
Siemensstr. 1
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3004977335

Location of Manufacturing Site (2)
SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD
278 Zhou Zhu Rd
Shanghai, CHINA, 201318
Establishment Registration Number:
3003202425

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)
(865) 218-3019 FAX

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:	SOMATOM Force

510(k) Number:	K190578
Clearance Date:	June 27, 2019
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.cite, Scan&GO

510(k) Number:	K200524
Clearance Date:	April 01, 2020
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All predicate device recalls have been considered in the subject device design.

Note: K200524 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 and Scan&GO software.

In this submission, the primary predicate device SOMATOM Force and the secondary predicate device SOMATOM X.cite including Scan&GO are being used, to demonstrate substantial equivalence of technological characteristics.

IV. Device Description

Siemens intends to market a new CT scanner system **NAEOTOM Alpha** supporting software version, SOMARIS/10 syngo CT VA40 with mobile workflow options.

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 VA40 is a dual-source Computed Tomography (CT) x-ray system featuring two detectors based on new 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 predicate devices, but support with improved technological characteristics.

The NAEOTOM Alpha with Software SOMARIS/10 syngo CT VA40 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, treatment preparation and therapy planning support (including, but not limited to, Brachytherapy, Particle including Proton Therapy, External Beam Radiation Therapy, Surgery). The computer system delivered with the CT scanner is able to run optional post processing applications.

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.

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 VA40 (SOMARIS/10 syngo CT VA40), 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 VA40 (SOMARIS/10 syngo CT VA40) is a modified software version based on syngo CT VA30A (SOMARIS/10 syngo CT VA30) which was cleared for the secondary predicate device and supports the same plugin interfaces for the subject device Scan&GO mobile workflow and integration of post-processing tasks as the secondary predicate device Scan&GO cleared in (K200524).

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 physician as an aid in diagnosis.
The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

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 comparable technological characteristics in terms of materials, energy source, and control mechanisms when compared to the primary predicate device SOMATOM Force. The software and hardware components of this scanner have been modified or improved in comparison to the predicate devices to support enhanced device functionality and a to introduce a new detector technology.

The subject device NAEOTOM Alpha is building on the dual-source CT system configuration of the primary predicate device SOMATOM Force.

NAEOTOM Alpha features comparable technological characteristics of a Siemens dual-source CT system, such as fast scan speed and temporal resolution down to 66ms. It uses the same general geometric dimensions of the measurement field (such as detector z coverage and scan-field-of-view) in comparison to the primary predicate device SOMATOM Force CT scanner system.

As a dual source CT scanner system, the primary predicate device SOMATOM Force features two conventional energy-integrating detectors made of scintillator ceramic (product marketing name “Ultra Fast Ceramic”, abbreviated UFC, based on scintillator ceramic). The subject device NAEOTOM Alpha features two photon counting detectors built from Cadmium-Telluride (CdTe).

Supported by the subject device, SOMARIS/10 syngo CT VA40 software version is a further development of the SOMARIS/10 syngo CT VA30 software version which is cleared in K200524.
It reuses all unmodified software features of the legacy software syngo CT VA30 as described below in the section “Unmodified Features used in the Subject Devices”.

As with the secondary predicate device SOMATOM X.cite, the subject device NAEOTOM Alpha is supported by an optional mobile workflow, Scan&GO. Scan&GO has been modified to add new iPad hardware and operating software that supports the application software installation.

Software version SOMARIS/10 syngo CT VA40 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 predicate devices.

At a high level, the subject device NAEOTOM Alpha and the primary predicate device SOMATOM Force or the secondary predicate device SOMATOM X.cite 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 SOMATOM Force or the secondary predicate device SOMATOM X.cite:

- Software version SOMARIS/10 syngo CT VA40
- Support updated cybersecurity features
- Additional options for Inline and GO technologies
- Iterative Reconstruction Methods
- **QuantaMax** Detector based on Quantum Technology

The following technological differences exist between the subject device Scan&GO mobile application software and the secondary predicate device Scan&GO mobile application software cleared in K200524:

- Software version SOMARIS/10 syngo CT VA40
- iPad hardware to support mobile workflow options

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

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

Table 01: Overview 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 devices
Unmodified	This feature remains unchanged from the predicate device
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 VA40 and is substantially equivalent compared to the cleared version.

New/modified hardware features:

Table 02: Overview of hardware modifications of NAEOTOM Alpha

		Subject Device
	Hardware properties supported by SOMARIS/10 syngo CT VA40	**NAEOTOM Alpha**
01	Detector - QuantaMax	new
02	Tablet hardware for Scan&GO - iPad	modified
03	Patient Table Configuration	modified

New software version SOMARIS/10 syngo CT VA40 with enabled, modified and new software features:

Table 03: Overview of software modifications of NAEOTOM Alpha

		Subject Device
	Software properties supported by SOMARIS/10 syngo CT VA40	**NAEOTOM Alpha**
01	Precision Matrix (1024²) (large image matrices)	enabled
02	Quantum Iterative Reconstruction	new
03	Always Dual Energy	new
04	Calcium scoring with keV images	modified
05	Imaging – Cardio BestPhase	enabled
06	CARE keV	new
07	Quantum Pure Lumen	new
08	Cardiac CT imaging - Motion artifact reduced ECG-gated imaging	modified
09	Motion artifact reduced non-gated imaging	modified

		Subject Device
	Software properties supported by SOMARIS/10 syngo CT VA40	**NAEOTOM Alpha**
10	myExam Console and myExam Satellite	modified
11	Recon&GO Inline Results - DE SPP	modified
12	Recon&GO Spectral Recon	modified

A tabular summary of the comparable hardware and software properties between the subject device NAEOTOM Alpha with software version syngo CT VA40 and predicate devices are listed in **Table 04 and Table 05** below (only the changes from the predicate devices are highlighted in gray in the sections below sections).

Table 04: NAEOTOM Alpha comparable hardware properties (**modified**)

Hardware properties	**subject device**	**primary predicate device**	**secondary predicate device**
	NAEOTOM Alpha Dual Source	**SOMATOM Force** Dual Source	**SOMATOM X.cite** Single Source
Scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner
Generator max. power	2x 120 kW	2x 120 kW	105 kW
Detector technology	Direct Conversion with "Quantum Technology"	Energy-integrating	Energy-integrating
Detector volume coverage	2 x 57.6 mm	2 x 57.6 mm	38.4 mm
Detector physical rows	2 x 288	2 x 96	64
Detector slice width	0.2 mm	0.6 mm	0.6 mm
Detector channel No.	2752 (A system) 1984 (B system)	920 (A system) 640 (B system)	840
X-ray Tube	Vectron	Vectron	Vectron
Tube kV steps	90 kV, 100 kV, 120 kV, 140 kV	(in 10kV steps) 70 kV to 150kV	(in 10kV steps) 70 kV to 150kV
Tube max. current	2 x 1300 mA	2 x 1300 mA	1200 mA
Tube tube focus	0.4×0.5 mm / 0.6x0.7 mm / 0.8x1.1 mm (for both tubes)	0.4×0.5 mm / 0.6×0.7 mm / 0.8x1.1 mm (for both tubes)	0.6x0.7 mm / 0.8x1.1 mm
Tube heat capacity	higher than 30 MHU	higher than 30 MHU	higher than 30 MHU
Tube Collimator	adaptive dose shied supported	adaptive dose shied supported	adaptive dose shied supported
Gantry bore size	82 cm	78 cm	82 cm
Gantry Scan FoV	50 cm	50 cm	50 cm
Gantry rotation time (sec)	0.25s; 0.5s; 1.0s;	0.25s, 0.285s, 0.33s, 0.5s, 1.0s	0.3s, 0.5s, 1.0s
Gantry Tilt (degree)	N/A	N/A	+/- 25
Patient Table type	Vario 2.D: 2000 mm, Vitus: 2000 mm	PHS5, MPT4: 1600 mm or 2000 mm	Vario RT: 1600 mm, Vario 2: 2000 mm
Max. Scan length Topogram	Vario 2.D: 2080 mm, Vitus: 2080 mm	1600 mm, 2000 mm	1680 mm, 2080 mm
Max. Scan length Image acquisition	Vario 2.D: 2000 mm, Vitus: 2000 mm	1600 mm, 2000 mm	1600 mm, 2000 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

Table 05: NAEOTOM Alpha comparable software properties

Properties software	**subject device**	**primary predicate device**	**secondary predicate device**
	NAEOTOM Alpha	**SOMATOM Force**	**SOMATOM X.cite**
	(syngo CT VA40)	**(K190578) (syngo CT VB20)**	**(K200524)**
Operating System	Windows based SOMARIS/10 syngo CT VA40	Windows based SOMARIS/7 syngo CT VB20	Windows based SOMARIS/10 syngo CT VA30 A
Acquisition Workplace	syngo Acquisition Workplace (AWP)	syngo Acquisition Workplace (AWP)	syngo Acquisition Workplace (AWP)
	syngo Viewing, syngo Filming and syngo Archiving & Networking	syngo Viewing, syngo Filming and syngo Archiving & Networking	syngo Viewing, syngo Filming and syngo Archiving & Networking
	2nd Acquisition Workplace supported with myExam Satellite	2nd Acquisition Workplace: RRWP	No 2nd Acquisition Workplace supported
IRS	Image Reconstruction from photon counting data	Image Reconstruction from classic Siemens dual source CT scanner	Image Reconstruction from classic Siemens single source CT scanner
Detector	QuantaMax detector firmware supported	Stellar 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 • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition	Support of: • Protocols for Radiation Therapy Planning • Protocol supporting contrast bolus-triggered data acquisition • Contrast protocols – CARE Contrast III • Pediatric Protocols • Flex Dose Profile • Turbo Flash Spiral • Dual Energy acquisition • Adaptive 4D Spiral • Protocols that allow scanning with support of an 3rd party respiratory gating system (ANZAI, Varian RGSC)	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocol supporting contrast bolus-triggered data acquisition • Contrast media protocols • Pediatric Protocols • Flex Dose Profile • TwinBeam DE • TwinSpiral DE • Flex 4D Spiral • Protocols that allow scanning with support of an 3rd party respiratory gating system (ANZAI, Varian RGSC)
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)	Advanced reconstruction tools supported: The syngo acquisition workplace provides, image reconstruction, and routine postprocessing. Various advanced reconstruction features supported by the CT Scanner, e.g., FAST and CARE applications.	Advanced reconstruction tools supported via Recon&GO_ - Spectral Recon (Dual Energy Reconstruction) - Inline Results DE SPP (Spectral Post-Processing) / including Virtual Unenhanced, Monoenergetic plus - Inline Results DE Ranges (Parallel/Radial) / Inline DE
Post-Processing	Software Plugin functions enabled via software interface Recon&GO - Inline Results various methods of cleared software applications	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 images. It can be used as a standalone device or together with a variety of	Software Plugin functions enabled via software interface Recon&GO - Inline Results various methods of cleared software applications

Properties software	subject device NAEOTOM Alpha (syngo CT VA40)	primary predicate device SOMATOM Force (K190578) (syngo CT VB20)	secondary predicate device SOMATOM X.cite (K200524)
		cleared and unmodified syngo based software options.	
Cybersecurity	IT Hardening	IT Hardening	IT Hardening
Standard Technologies	• FAST Features • CARE Features • GO technology	• FAST Features • CARE Features	• FAST Features • CARE Features • GO technology
	• CARE keV	• CARE kV	• CARE kV
Iterative Reconstruction Methods	Quantum Iterative Reconstruction	iMAR, SAFIRE, ADMIRE	iMAR, ADMIRE
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)	Matrix resolution 512x512 (auto mode not supported)
Ca Scoring	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 Force 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.	Classic SOMATOM X.cite 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. Siemens believes that the subject device is substantially equivalent to the predicate devices. Testing and validation are completed. Test results show that the subject device, the NAEOTOM Alpha, is comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore is substantially equivalent to the primary predicate SOMATOM Force and secondary predicate device SOMATOM X.cite.

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 tests 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 **07** below.

Table 06: Non-Clinical Performance Testing

#	Feature	Non-Clinical Performance Testing
01	Quantum Iterative Reconstruction	Quantum Iterative Reconstruction - QIR is routinely used in all reconstructions on the subject device NAEOTOM Alpha. As with the primary predicate device SOMATOM Force supporting ADMIRE, the subject device supports iterative reconstruction principle. NAEOTOM Alpha supports Quantum Iterative Reconstruction with image data generated with Quantum Technology (QuantaMax Detector) and optimized for photon counting data. Iterative Beam Hardening Correction - IBHC is an iterative Beam Hardening Correction algorithm optimized for the subject device NAEOTOM Alpha. Performance testing was done to support all technological characteristics, that are associated with this new technology.
02	Detector – QuantaMax	The subject device NAEOTOM Alpha supports two “QuantaMax” detectors for CT data acquisition. The QuantaMax detectors are built on the new “Quantum Technology” which is Siemens Healthineers’ implementation of photon counting technology for CT detectors. The performed tests include the measurement and analysis of raw data for single photon counting, the nonexistence of classical noise and the ability to measure multiple energies simultaneously. Furthermore, the performance evaluation provides an in-depth evaluation of NAETOM Alpha Image Quality for general CT imaging, based on phantom evaluation of Typical Modes, compared to the predicate device SOMATOM Force. It also includes parameters for supporting the suitability of the subject device for low dose lung cancer screening.
05	Cardiac CT imaging - Motion artifact reduced ECG-gated imaging	As with the primary predicate device the subject device supports ECG-gated imaging based on ECG-controlled dose modulation and triggering derived from continuous monitoring of the ECG. With same technological principle as cleared with the primary predicate device, the subject device supports with an unmodified algorithm, the desired prediction of the target start- and stop phase in retrospective spiral and in sequence mode. The prediction of the start phase in ECG triggered high pitch scanning is modified to improve the prediction over a wider range of heart rates. The associated test evidence contains a basic test scenario and the results of measurements based on an andromorphic motion heart phantom to support the clinical approach based on technical phantom measurements, which are to some extend clinically realistic.
06	CARE keV	CARE kV is supported by the primary predicate device SOMATOM Force. The subject device NAEOTOM Alpha based on Quantum Technology supports CARE keV. CARE keV takes the dose efficiency of Monoenergetic reconstructions into account, by automatically adjusting the appropriate kV and effective mAs settings to optimize the applied dose while the image quality is maintained. The test procedure includes phantom measurements with clinically relevant phantom diameters and contrast materials to support the contrast, noise, and radiation dose related CARE keV information.
07	Quantum Pure Lumen	The subject device NAEOTOM Alpha supports with its new feature “VCR – Pure Lumen” a modified algorithm, which allows to reconstruct with a virtual removal of calcium in spectral generated images with a possible application in heavily calcified vessels. Algorithm, clinical references and example images derived from phantom based measurements. Performance testing was done to support all technological characteristics, that are associated with this new technology.

#	Feature	Non-Clinical Performance Testing
08	Always Dual Energy	The subject device NAEOTOM Alpha supports virtual monochromatic images, virtual non-contrast images and iodine images for all QuantumPlus scans, i.e., all scans with 120kV or 140kV without tin filtration and not in UHR mode. Performance testing was done to assess the accuracy of these three image types on phantoms with iodine inserts.
09	Motion artifact reduced non-gated imaging	As with the primary predicate device SOMATOM Force the subject device supports spiral scanning at different pitch value of up to 3.2 in a dual source acquisition and up to 1.5 in a single source acquisition. These acquisitions at high pitch values and therefore table speeds have the potential to minimize motion artifacts. This feature name and detector hardware is modified. In comparison to the primary predicate device SOMATOM Force, other technological characteristics to support the feature remains unmodified. Performance testing was done to confirm the characteristics to allow improvement of motion artifacts. It also contains a basic test scenario and the results of measurements based on an andromorphic motion heart and respiratory phantom to support the clinical approach based on technical phantom measurements, which are clinically realistic.
10	Calcium Scoring with keV Images	As with the primary predicate device SOMATOM Force, the subject device support CaScoring. With its photon counting detector technology, the subject device software is modified to use its generated monoenergetic images as a base for calcium scoring. The performance evaluation used monoenergetic images reconstructed at 70 keV with different QIR strength settings derived from a counting detector technology acquisition of the subject device NAEOTOM Alpha, which are suitable in the application of Agatston Score base Coronary Calcium scoring.

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 07** and **Table 08** below.

Table 07: 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 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

Date of Recognition	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				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 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 08: 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.
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 09** below.

Table 09: 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 with 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 predicate devices were cleared based on the results of non-clinical testing including verification and validation, phantom tests, and supportive literature. The subject device is also tested using the same test methods and workflows as used for the predicate devices. 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 predicate devices currently marketed for the same intended use. Since the subject and predicate devices were tested using the same methods, Siemens believes that the data generated from the NAEOTOM Alpha testing supports a finding of substantial equivalence.