December 6, 2023

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

Re: K232206
Trade/Device Name: SOMATOM Pro.Pulse
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: November 8, 2023
Received: November 8, 2023

Dear Clayton Ginn:

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 Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232206

Device Name
SOMATOM Pro.Pulse

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 trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.
This CT system can be used for low dose lung cancer screening in high risk populations*.
*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

for

SOMATOM Pro.Pulse – Software Version SOMARIS/10 *syngo* CT VB10

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. Contact Details

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 (1)
Siemens Healthcare GmbH
Siemensstr. 1 -OR- Rittigfeld 1
D-91301 Forchheim, Germany
Establishment Registration Number: 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.

Submitter Contact Person:
Clayton Ginn
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
Molecular Imaging
810 Innovation Drive
Knoxville, TN 37932
Phone: (865) 898-2692
clayton.ginn@siemens-healthineers.com

Backup Contact
Alaine Medio
Regulatory Affairs Manager
Siemens Medical Solutions USA, Inc.
Molecular Imaging
810 Innovation Drive
Knoxville, TN 37932
Phone: (865) 206-0337
alaine.medio@siemens-healthineers.com

II. Device Name and Classification

Product name:	SOMATOM Pro.Pulse
Trade name:	SOMATOM Pro.Pulse
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:	SOMATOM go.Top
510(k) Number:	K211373
Clearance Date:	August 27, 2021
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All predicate device recalls have been considered in the subject device design.

Reference device:

Trade Name:	SOMATOM Drive
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.

IV. Device Description Summary

Siemens intends to market a new Dual Source CT scanner system SOMATOM Pro.Pulse based on the SOMARIS/10 platform.

The subject device SOMATOM Pro.Pulse with software version SOMARIS/10 *syngo* CT VB10 is a Computed Tomography X-ray system which features two continuously rotating tube-detector system (dual source) and functions according to the fan beam principle. The SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10 produces CT images in DICOM format. The images delivered by the system can be used by trained staff for post-processing applications commercially distributed by Siemens Healthcare and other vendors as an aid in diagnosis, treatment preparation, radiation therapy planning, and diagnostic and therapeutic interventions (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.

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 SOMATOM Pro.Pulse is 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 predicate device, *syngo* CT VA40 (SOMARIS/10 *syngo* CT VA40) cleared in K211373.

The subject device SOMATOM Pro.Pulse will support previously cleared software and hardware features in addition to the applicable modifications as described within this submission. The intended use remains unchanged compared to the predicate devices.

V. Indications for Use

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

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

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

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

VI. Indications for Use Comparison

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 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.

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 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 reference predicate's Indications for Use (K230421), however it is slightly different than the primary predicate's Indications for Use.

2. The sentence "The images delivered by the system can be used by a trained physician as an aid in diagnosis" was removed, since the subsequent sentence restates the same, replacing 'trained physician' with 'trained staff'. It can be assumed a trained physician is part of the trained staff.

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.

3. The word 'preparation' has been removed from the phrase "treatment preparation and radiation therapy planning" since treatment planning better describes how the device is used.

4. The phrase "as well as for diagnostic and therapeutic interventions" was added to the second sentence. This was done to express use of the device in standard practice. The predicate device can and is commonly used as an aid in invasive procedures. The same is applicable to the subject device.
None of the intended use includes 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 SOMATOM CT System 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 VA40 software version which is cleared in K211373.

The SOMATOM Pro.Pulse 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 SOMATOM Pro.Pulse have been modified or improved in comparison to the predicate devices to support enhanced device functionality compared to the predicate devices.

The intended use and fundamental scientific technology for the SOMATOM Pro.Pulse remain unchanged from the predicate devices.

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

- Scanner Principle- Whole body X-Ray Computed Tomography Scanner
- System Acquisition – Continuously rotating tube detector system
- Workplaces – Support of workplaces that include reconstruction and image evaluation software
- Patient table
- Patient table foot switch for movement
- Tin filtration technology
- Stellar detector technology
- Athlon type X-ray tube
- Power generator
- High Power 80/ High Power 70
- Iterative reconstruction methods
- Scan&GO
- Mobile workflow (Tablets)
- Optional injector arm
- Support of CT guided intervention workflow (myNeedle Guide)
- Precision matrix (large image matrices)
- DirectDensity™ Reconstruction
- Cardiac CT imaging

The subject device SOMATOM Pro.Pulse 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.

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

Table 1: Overview of term definition

Term	Definition
N/A	The feature is not supported for the subject device
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

Term	Definition
	subject device with software version SOMARIS/10 syngo CT VB10 and is substantially equivalent compared to the cleared version of the predicate/reference device.
modified	This feature is a modified form of a feature cleared within the predicate and/ or reference devices
new	The feature is newly supported for Siemens CT Scanners and the subject device

1) Modified Hardware

Table 2: Overview of hardware modifications for the subject device SOMATOM Pro.Pulse with SOMARIS/10 syngo CT VB10 compared to the predicate/reference devices.

#	Hardware properties	SOMATOM Pro.Pulse SOMARIS/10 *syngo* CT VB10
1.	CARE Breathe	enabled
2.	FAST 3D Camera	modified
3.	Full-range CARE 2D Camera	modified
4.	Moodlight	modified
5.	CARE Moodlight	modified
6.	Patient table configuration	modified

2) Modified Software (*syngo* CT VB10)

Table 3: Overview of software modifications for the subject device SOMATOM Pro.Pulse with SOMARIS/10 syngo CT VB10 compared to the predicate/reference devices.

#	Software properties	SOMATOM Pro.Pulse SOMARIS/10 *syngo* CT VB10
1.	ZeeFree	new
2.	Dual Source Dual Energy	enabled
3.	FAST Integrated Workflow	modified
4.	Automatic Patient Instruction	modified
5.	myNeedle Guide (with MyNeedle Detection)	modified
6.	CARE kV	modified
7.	Recon&GO	modified
8.	CT View&GO	modified
9.	myExam Companion – myExam Compass/myExam Cockpit	modified

#	Software properties	SOMATOM Pro.Pulse SOMARIS/10 *syngo* CT VB10
10.	Scan&GO	enabled
11.	Flex4D Spiral – Neuro/Body	modified

A tabular summary of the comparable hardware properties between the subject and predicate/reference devices is provided in the following Table 4 and Table 5.

Table 4: Technical hardware characteristics for subject device SOMATOM Pro.Pulse (software version SOMARIS/10 syngo CT VB10) compared to the predicate/reference devices.

Hardware property	**Subject device** **SOMATOM Pro.Pulse** **with SOMARIS/10 *syngo* CT VB10**	**Primary predicate device** **SOMATOM go.Top** **with SOMARIS/10 *syngo* CT VA40** **(K211373)**	**Reference device** **SOMATOM Drive** **with SOMARIS/7 *syngo* CT VB30** **(K230421)**
scanner	Whole body Computed Tomography (CT) Scanner System	Whole body Computed Tomography (CT) Scanner System	Whole body Computed Tomography (CT) Scanner System
System configuration	Dual Source	Single Source	Dual Source
Environment of Use	Professional Healthcare Facility	Professional Healthcare Facility	Professional Healthcare Facility
Generator Max. power (kW)	150 (2 x 75)	75	200 (2 x 100)
Detector technology	Stellar detector based on Multislice UFC (Ultra Fast Ceramic)	Stellar detector based on Multislice UFC (Ultra Fast Ceramic)	Stellar^{Infinity} Detector (UFC detector) with TrueSignal and Edge technology
Detector volume coverage	38.4 mm	38.4 mm	32 mm
Detector physical rows	2 x 64	64	2 x 64
Detector Slice width	0.6 mm	0.6 mm	0.5 mm
Detector	840 (detector A)	840	1472 (detector A)

Hardware property	Subject device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10	Primary predicate device SOMATOM go.Top with SOMARIS/10 *syngo* CT VA40 (K211373)	Reference device SOMATOM Drive with SOMARIS/7 *syngo* CT VB30 (K230421)
DAS channel no.	600 (detector B)		960 (detector B)
Detector **Image slices**	2 x 128 (with Interleaved Volume Reconstruction, IVR) 2 x 384 (reconstructed slices)	128 (with Interleaved Volume Reconstruction, IVR) 384 (reconstructed slices)	2 x 128 (acquired slices through z-Sharp technology) 2 x 384 (reconstructed slices)
Tube **technology**	2 x Athlon® DS X-ray tube	Athlon® X-ray tube	2 x Straton MX Sigma X-ray tubes
Tube **collimator**	Tube collimator DS4-A, DS4-B • Equivalent to 0.5 mm Al in the isocenter • 1 mm Al with cardio wedge	Tube collimator • Equivalent to 0.5 mm Al in the isocenter • 1 mm Al with cardio wedge	Detector Scatter Collimator For improved low-contrast resolution, e.g., in neuro and abdominal imaging
Tube **kV steps**	70–140 kV in 10 kV steps	70–140 kV in 10 kV steps	70–140 kV in 10 kV steps
Tube **Max. current**	Single Source: 13-825 mA Dual Source: 26-1650 mA	Standard range: 13 – 825 mA	Single source 20–800 mA Dual source 40–1600 mA
Tube **focus**	• 0.8 × 0.8 / 7° • 1.0 × 1.2 / 7°	• 0.8 × 0.8 / 7° • 1.0 × 1.2 / 7°	• 0.7 x 0.7/7° • 0.9 x 1.1/7°
Tube **Heat storage capacity**	2 x 7.0 MHU	7.0 MHU	0 MHU (0.6 MHU capacity combined with 7.3 MHU/min (5,400 kJ/min) cooling rate is comparable to the performance of a conventional tube with approximately 50 MHU (37,000 kJ) anode heat storage capacity)
Tube **Cooling rate (MHU/ min)**	up to 1.7	up to 1.7	7.3

Hardware property	Subject device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10	Primary predicate device SOMATOM go.Top with SOMARIS/10 *syngo* CT VA40 (K211373)	Reference device SOMATOM Drive with SOMARIS/7 *syngo* CT VB30 (K230421)
Gantry **Bore size**	70	70	78
Gantry **Scan FoV (cm)**	50	50	50
Gantry **Extended FoV (cm)**	70	70	78
Gantry **Rot. time (sec)**	0.33 (optional), 0.5, 1.0	0.33 (optional), 0.5, 1.0	0.28, 0.33, 0.5, 1.0
Gantry **Tilt (degree)**	n.a.	± 30°	n.a.
Maximum temporal resolution in ECG gated or triggered examination **(ms)**	86 ms (mono-segment) 43 ms (bi-segment)	165 ms (mono-segment) 82.5 ms (bi-segment)	75 ms (mono-segment) 37.5 ms (bi-segment)
Maximum scan speed at pitch **(mm/s at pitch x)**	372 mm/s at pitch 3.2	175 mm/s at pitch 1.5	458 mm/s at pitch 3.4
Touch panels	Yes	Yes	Yes
Patient table **Type**	Vario 2 (2000 mm) Vario 2.D (2000 mm)	Vario1 (1600 mm) Vario RT (1600 mm) Vario 2 (2000mm)	PHS 2000 (type PHS4n) Multi-purpose patient (MPT) table (optional)
Patient table **Max. weight capacity (kg)**	307	227 307	227 307
Max. scan length topogram	2080 mm with table extension	1680 mm with table extension 2080 mm with table extension	2000 mm

Hardware property	Subject device SOMATOM Pro.Pulse with SOMARIS/10 *syngo* CT VB10	Primary predicate device SOMATOM go.Top with SOMARIS/10 *syngo* CT VA40 (K211373)	Reference device SOMATOM Drive with SOMARIS/7 *syngo* CT VB30 (K230421)
Max. scan length **Image acquisition**	Max. 2000 mm with patient table extension	Max. 1600 mm with patient table extension Max. 2000 mm with patient table extension	Max. 1840 mm
Spectral filtration	Tin Filter	Combined Tin Filter / Split Filter	Tin Filter
FAST 3D Camera	option for patient positioning with 3D Camera: • Ceiling mounted • Gantry mounted	option for patient positioning with 3D Camera: • Ceiling mounted	option for patient positioning with 3D Camera: • Ceiling mounted
High Power 70/ High Power 80	up to 825 mA (@70 kV) up to 825 mA (@80 kV)	up to 825 mA (@70 kV) up to 825 mA (@80 kV)	750 mA (@ 80 kV) 650 mA (@ 70 kV)
x-ray foot switch	Option to trigger hands-free scanning	Option to trigger hands-free scanning	Option to trigger hands-free scanning
Table foot switch	Option for table patient movement	Option for table patient movement	N/A
i-joystick	Option for patient table movements, including an electrical connection for the tablet dock which allows charging the tablet when mounted.	Option for patient table movements, including an 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.
Tablet dock	Option for mounting of the tablet on the patient table.	Option for mounting of the tablet on the patient table.	N/A

Table 5: Technical software characteristics for subject device SOMATOM Pro.Pulse (software version SOMARIS/10 syngo CT VB10) compared to the predicat/reference devices.

Software property	**Subject device**	**Primary predicate device**	**Reference device**
	SOMATOM Pro.Pulse **SOMARIS/10 *syngo* CT VB10**	**SOMATOM go.Top** **SOMARIS/10 *syngo* CT VA40** **(K211373)**	**SOMATOM Drive** **SOMARIS/7 *syngo* CT VB30** **(K230421)**
Operating System	Windows based SOMARIS/10 *syngo* CT VB10 Note: Note: the short version *syngo* CT VB10 is also used as labeling information	Windows based SOMARIS/10 *syngo* CT VA40 Note: Note: the short version *syngo* CT VA40 is also used as labeling information	Windows based SOMARIS/7 *syngo* CT VB20 Note: Note: the short version *syngo* CT VB20 is also used as labeling information
Acquisition Workplace	*syngo* Acquisition Workplace named as "myExam Console" *syngo* Viewing, *syngo* Filming and *syngo* Archiving & Networking Image Reconstruction (IRS) 2nd Acquisition Workplace named as "myExam Satellite"	*syngo* Acquisition Workplace named as "myExam Console" *syngo* Viewing, *syngo* Filming and *syngo* Archiving & Networking Image Reconstruction (IRS) 2nd Acquisition Workplace named as "myExam Satellite"	*syngo*® Acquisition Workplace (AWP) optional second operating console (RRWP)
Teamplay	Support of Teamplay protocols	Support of Teamplay protocols	Support of Teamplay protocols
Protocols	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocols supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile	Support of: • Protocols for Radiation Therapy Planning support patient marking • Protocols supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Flex Dose Profile	Support of: • Protocols for Radiation Therapy Planning • Protocols supporting contrast bolus-triggered data acquisition • Contrast media protocols (including coronary CTA) • Pediatric Protocols • Dual Source Dual Energy protocols • Dual Source Dual Energy protocols for Radiation Therapy Planning

Software property	Subject device	Primary predicate device	Reference device
	SOMATOM Pro.Pulse **SOMARIS/10 *syngo* CT VB10**	**SOMATOM go.Top** **SOMARIS/10 *syngo* CT VA40** **(K211373)**	**SOMATOM Drive** **SOMARIS/7 *syngo* CT VB30** **(K230421)**
	• Dynamic imaging (Flex 4D Spiral) • interventional scan protocols (scan modes: i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution • Turbo Flash Spiral • various i-spiral and i-sequence scan protocols (applying different scanning parameters such as different slice thicknesses, kV settings or reconstructions kernels to support different clinical scenarios) and using features like iMAR, CARE Dose4D and CARE kV • TwinkV (Dual Source Dual Energy acquisition)	• Dynamic imaging (Flex 4D Spiral) • interventional scan protocols (i-sequence, i-spiral, i-Fluoro) • Protocols supporting Cardiac Scanning, Spectral imaging for child examination, Spectral imaging with high resolution • Turbo Flash Spiral • various i-spiral and i-sequence scan protocols (applying different scanning parameters such as different slice thicknesses, kV settings or reconstructions kernels to support different clinical scenarios) and using features like iMAR, CARE Dose4D and CARE kV • TwinBeam (Single Source Dual Energy acquisition) • TwinSpiral (Single Source Dual Energy acquisition) • Protocols that allow scanning with support of an external respiratory gating system (ANZAI, Varian RGSC)	• Protocols for CT intervention • Protocols that allow triggering of breath hold scanning from external devices • ECG gated Flash protocols

Software property	Subject device	Primary predicate device	Reference device
	SOMATOM Pro.Pulse **SOMARIS/10 *syngo* CT VB10**	**SOMATOM go.Top** **SOMARIS/10 *syngo* CT VA40** **(K211373)**	**SOMATOM Drive** **SOMARIS/7 *syngo* CT VB30** **(K230421)**
Advanced Reconstruction	Recon&GO: - DE SPP (Spectral Post-Processing) - Spectral Recon (Dual Energy Reconstruction including None, low (L3D) and high (H3D) energy images) - Inline Anatomical ranges (Parallel/Radial) incl. Virtual Unenhanced, Monoenergetic plus - Inline Spine and Rib Ranges - Inline table and bone removal	Recon&GO: - DE SPP (Spectral Post-Processing) - Spectral Recon (Dual Energy Reconstruction including, None, low (L3D) and high (H3D) energy images, Virtual Unenhanced, Monoenergetic plus)	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.
Post-Processing interface	• Recon&GO Inline Results: Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices 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	• Recon&GO Inline Results: Software interface to post-processing algorithms which are unmodified when loaded onto the CT scanners and 510(k) cleared as medical devices 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	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 cleared and unmodified syngo based software options.

Software property	Subject device	Primary predicate device	Reference device
	SOMATOM Pro.Pulse **SOMARIS/10 *syngo* CT VB10**	**SOMATOM go.Top** **SOMARIS/10 *syngo* CT VA40** **(K211373)**	**SOMATOM Drive** **SOMARIS/7 *syngo* CT VB30** **(K230421)**
	software is mandatory precondition. These advanced visualization tools are designed to support the technician & physician in the qualitative and quantitative measurement & analysis of clinical data acquired and reconstructed by Computed Tomography scanners. Additional information regarding the points of interface and inputs for this feature is provided in Section 16.	software 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.	
CT View&GO	- 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing - Interactive Spectral Imaging (ISI) - Basic visualization tools: Endo View - Basic manipulation tools: DE ROI, ROI HU, Average	- 2D and 3D (MPR, VRT, MIP and minIP) - Evaluation tools, Filming, Printing	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 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 • GO technology	• FAST Features • CARE Features
Iterative Reconstruction Methods	ADMIRE iMAR	ADMIRE iMAR SAFIRE	ADMIRE iMAR SAFIRE
HD FoV	HD FoV 4.0	HD FoV 4.0	HD FoV 4.0

Software property	Subject device	Primary predicate device	Reference device
	SOMATOM Pro.Pulse **SOMARIS/10 *syngo* CT VB10**	**SOMATOM go.Top** **SOMARIS/10 *syngo* CT VA40** **(K211373)**	**SOMATOM Drive** **SOMARIS/7 *syngo* CT VB30** **(K230421)**
Matrix sizes	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision matrix)	256 x 256 pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision matrix)	256 x 256pixels 512 x 512 pixels 768 x 768 pixels 1024 x 1024 pixels (Precision matrix)
DirectDensity™	DirectDensity™ Image values can be interpreted as showing relative electron density or relative mass density, independent from tube voltage and beam filtration settings	DirectDensity™ Image values can be interpreted as showing relative electron density or relative mass density, independent from tube voltage and beam filtration settings	DirectDensity™ Image values can be interpreted as showing relative electron density or relative mass density, independent from tube voltage and beam filtration settings

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation are completed. Test results show that the subject device SOMATOM Pro.Pulse 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 SOMATOM Pro.Pulse 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 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**
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 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.

Feature/Non-clinical supportive testing	Bench Testing performed
	• 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
Dual Source Dual Energy	The bench test verifies the successful implementation of the Dual Source Dual Energy (DSDE) scan mode on the SOMATOM Pro.Pulse with the two voltage combinations: - 80 kV / Sn140 kV (80/Sn140 kV) - 100 kV / Sn140 kV (100/Sn140 kV) Image quality and spectral properties are evaluated based on phantom studies using ex-factory scan protocols for head and abdomen. The presented evaluation includes low-kV and high-kV images as well as Mixed images. The measurements show that the spectral characteristics of the system in terms of iodine ratio are well comparable to the reference device SOMATOM Drive. All applied tests concerning image quality passed.
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 VA40 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 VA40. The FAST Isocentering accuracy of the subject device with *syngo* CT VB10 is comparable to the predicate device with syngo CT VA40, 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 VA40. In the gantry mounting position, the legs are often occluded by the torso when the patient is lying head-first on the table. This is not a severe limitation, as leg examinations are usually performed feet-first. 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 VA40 predicate for the new FAST 3D Camera hardware, also in the new gantry position.
myNeedle Guide	Tests were performed to ensure clinical usability of the myNeedle Guide needle detection algorithm. Two individual tests were performed. The accuracy of the

Feature/Non-clinical supportive testing	Bench Testing performed
(with myNeedle Detection)	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 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.
CARE kV	The bench test evaluates that the effective mAs settings of both the low and high kV acquisitions of a TwinkV scan (Dual Source Dual Energy scan mode) are adapted by CARE kV so that the image quality in terms of (CNR) is maintained. The image qualities (i.e. CNR values) of certain phantom under different kV settings in “Manual kV” mode are consistent. Using CARE kV for TwinkV, contrast, noise, and CNR values in the mix images are consistent for all voltage combinations. In all cases, CNR values do not deviate by more than 10% from the average CNR over the available voltage combinations.
Flex 4D Spiral – Neuro/Body	With Somaris/10 VB10, the F4DS mode is enabled on SOMATOM Pro.Pulse. F4DS requires a teamwork of several trajectories and curves - table trajectory, x-ray beam on trajectory, collimator trajectory, and reconstruction curve. No artifacts had been observed for any F4DS scan mode due to missing data, indicating that the trajectories work properly in hand. This also accounts for the scenario, where the user may change the pitch setting to get access to another range of scan coverages.
Low-Dose Lung Cancer Screening	The bench test provides a comparison of technical parameters specific to Low-Dose Lung Cancer Screening of the predicate and subject devices, following the established concept of our previous 510(k) submissions. It can be concluded that the subject and predicate devices are substantially equivalent for the task of Low-Dose Lung Cancer Screening since the bench test results showed comparable technical parameters.

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

Table 7: Recognized consensus standards.

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
12/19/2022	12-349	NEMA	PS 3.1 - 3.20 2022d	Digital Imaging and Communications in Medicine (DICOM) Set
07/06/2020	12-325	NEMA	XR 25-2019	Computed Tomography Dose Check
07/06/2020	12-330	NEMA	XR 28-2018	Supplemental Requirements for User Information and System Function Related to Dose in CT
12/23/2019	12-328	IEC	61223-3-5 Edition 2.0 2019-09	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests and constancy tests - Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
03/14/2011	12-226	IEC	61223-2-6 Second Edition 2006-11	Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment
01/14/2014	12-269	IEC	60601-1-3 Edition 2.1 2013-04	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
06/27/2016	12-302	IEC	60601-2-44 Edition 3.2: 2016	Medical electrical equipment - Part 2-44: Particular requirements for the basic

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				safety and essential performance of x-ray equipment for computed tomography
12/23/2019	5-125	ANSI AAMI ISO	14971: 2019	Medical devices - Applications of risk management to medical devices
		ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
01/14/2019	13-79	ANSI AAMI IEC	62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
		IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
07/09/2014	19-46	ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
09/17/2018	19-36	ANSI AAMI IEC	60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
		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

Date of Entry	Recognition Number	Standard Developing Organization	Standard Designation Number and Date	Title of Standard
				engineering to medical devices, including Amendment 1
		IEC	62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
07/09/2014	12-273	IEC	60825-1 Edition 2.0 2007-03	Safety of laser products - Part 1: Equipment classification, and requirements
12/21/2020	5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
12/23/2019	12-309	IEC	60601-2-28 Edition 3.0 2017-06	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
12/20/2021	12-341	IEC	62563-1 Edition 1.2 2021-07 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.

Standard Developing Organization	Standard Designation Number and Date	Title of Standard	How was Standard Used
IEC/ISO	17050-2	Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation.	General consensus standards not currently recognized by FDA.

A list of applicable guidance documents considered for this submission is provided as Table 9 below.

Table 9: FDA guidance document

FDA Guidance Document	Issue date
User Fees and Refunds for Premarket Notification Submissions (510(k)s): Guidance for Industry and Food and Drug Administration Staff	10/05/2022
Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff	04/21/2022
Format for Traditional and Abbreviated 510(k)s: Guidance for Industry and FDA Staff	09/13/2019
Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff	10/25/2017
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff	07/28/2014
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff	05/11/2005
Off-The-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff	09/27/2019
Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff	02/03/2016
Pediatric Information for X-ray Imaging Device Premarket Notifications: Guidance for Industry and Food and Drug Administration Staff	11/28/2017
Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff	10/02/2014
Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff	06/06/2022
Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices: Guidance for Industry and Food and Drug Administration Staff	09/06/2017
Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices: Guidance for Industry and Food and Drug Administration Staff	09/14/2018

Verification and Validation

Software documentation at an Enhanced Documentation level per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on June 14, 2023 is included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. 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. 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.

Wireless and Wireless Coexistence

Siemens SOMATOM Pro.Pulse conform 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 tablets 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 CT Scanners 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 the 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.

Additional Supportive Data

The National Lung Screening Trial (NLST), sponsored by the National Cancer Institute, is used to support the additional lung cancer screening Indications for Use. The study was a randomized trial of screening with the use of low-dose CT compared to chest radiography to determine whether screening with low-dose CT could reduce mortality from lung cancer. The study start date was August, 2002 and the completion date was October, 2010. The interpretation task with CT for this study was to detect lung nodules of 4mm diameter or greater.

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 the software specifications have met the predetermined 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 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 methods 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 subject device SOMATOM Pro.Pulse should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM Pro.Pulse perform comparably to the predicate devices currently marketed for the same intended use. Since all predicate devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM Pro.Pulse testing supports a finding of substantial equivalence.