



Food and Drug Administration
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Blvd., Mail Code 65-1A
MALVERN PA 19355

March 21, 2017

Re: K163296
Trade/Device Name: Somatom Go.up, Somatom Go.now
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 21, 2017
Received: February 23, 2017

Dear Ms. Mangum:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K163296

Device Name

Somatom Go.up, Somatom Go.now

Indications for Use (Describe)

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

The images delivered by the system can be used by a trained physician as an aid in diagnosis.

This CT system can be used for low dose lung cancer screening in high risk populations. High risk populations are 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 go. PLATFORM SCANNERS**

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: January 26, 2017

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

Importer/Distributor
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Establishment Registration Number
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Location of Manufacturing Site (1)

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Establishment Registration Number
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Location of Manufacturing Site (2)

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Shanghai, CHINA, 201318
Establishment Registration Number:
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II. Device Name and Classification

Product Name:	SOMATOM go.Now
Propriety Trade Name:	SOMATOM go.Now
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
Primary Product Code:	JAK
Secondary Product Code:	LLZ

Product Name: SOMATOM go.Up
Propriety Trade Name: SOMATOM go.Up
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
Primary Product Code: JAK
Secondary Product Code: LLZ

III. Predicate Device

Primary Predicate Device:

Trade Name: SOMATOM Perspective
510(k) Number: K142955
Clearance Date: November 24, 2015
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK
Recall Information: All applicable recalls are considered and addressed as part of the design control process

Secondary Predicate Devices:

Trade Name: SOMATOM Drive
510(k) Number: K161196
Clearance Date: August 24, 2016
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR § 892.1750
Device Class: Class II
Product Code: JAK
Recall Information: All applicable recalls are considered and addressed as part of the design control process

Trade Name: SOMATOM Scope

510(k) Number: K142955
Clearance Date: November 24, 2015
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR § 892.1750
Device Class: Class II
Product Code: JAK
Recall Information: All applicable recalls are considered and addressed as part of the design control process

IV. Device Description

The Siemens SOMATOM go. Platform is comprised of 2 Computed Tomography (CT) Scanner Systems, SOMATOM go.Now and SOMATOM go.Up. These CT scanners feature one continuously rotating tube-detector system and function according to the fan beam principle. The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The SOMATOM go.Now and SOMATOM go.Up scanners produce CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens and other vendors as an aid in diagnosis and treatment preparation. The computer system delivered with the CT scanner is able to run optional post processing applications.

The software version for the SOMATOM go.Now and SOMATOM go.Up scanners, syngo CT VA10A (SOMARIS/10 syngo CT VA10A), is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The software platform SOMARIS/10 syngo CT VA10A is designed to provide a plugin interface to integrate potential advanced post processing tasks, tools, or extendable functionalities.

The SOMATOM go.Now and SOMATOM go.Up will support the following modifications in comparison to the predicate devices:

- New Marketing Name: SOMATOM go.Now or SOMATOM go.Up
- New/Modified Hardware
- Gantry Mechanics (modified)
- Generator (modified)
- Patient Table (modified)
- Stellar Detector Technology (modified)
- Remote Scan Control (wired/wireless) (new)
- Control Box (modified)
- X-Ray Tube (modified)
- Software version SOMARIS/10 syngo CT VA10A
- Basic Post Processing Viewer (modified)
- Acquisition Application (modified)
- Image Reconstruction (modified)
- Interface for Advanced Post Processing Application (new)
- Interface for Plugin (for future advanced visualization tools and extended functionalities) (new)
- Interface to support an optional mobile workflow control application software (new)
- Update 510(k) Information

A comparison of these modifications with respect to the predicate devices is provided the “Comparison of Technological Characteristics with the Predicate Device” section below. As with the primary predicate device, the SOMATOM go.Now will be available in a 16 row 32 slice configuration. The SOMATOM go.Up will be available in a 32 row 64 slice configuration. Both the SOMATOM go.Now and the SOMATOM go.Up will include a UFC stellar-technology based detector system, with the SOMATOM go.Now supporting an 11.2 mm detector coverage in comparison to the SOMATOM go.Up which supports a 22.4 mm detector coverage. A summary of the differences between the SOMATOM go.Now and the SOMATOM go.Up is provided as **Table 1** below:

Table 1: Subject Device Comparable Properties

Key specifications	go.Now	go.Up
Physical Rows	16	32
Slice width (mm)	0.7	0.7
z coverage (mm)	11.2	22.4
Rotation time (s)	0.8, 1.0, 1.5	0.8, 1.0, 1.5
FoV (cm)	50	50
Max scan range (cm)	125	160
	160	
Bore size (cm)	70	70
Gantry tilt	NO	YES
Table Vertical Movement	Standard: No	YES
	Optional: YES	
Table Load (kg)	Table Load: 160	227
	Optional: 227	
Power (kW)	32	32
XTA X-ray Tube	Chronon	Chronon
Tube heat capacity (MHU)	3.5	3.5

Key specifications	go.Now	go.Up
Recon speed (images/s)	9 (optional 13)	13
CaScoring	N/A	optional
Detector width	11.2 mm	22.4 mm
Iterative Reconstruction Methods	SAFIRE, iMAR	SAFIRE, iMAR
Spiral Scan	yes	yes

V. Indications for Use

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data. The images delivered by the system can be used by a trained physician as an aid in diagnosis.

This CT system can be used for low dose lung cancer screening in high risk populations. High risk populations are 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. Comparison of Technological Characteristics with the Predicate Device

The SOMATOM go.Now and SOMATOM go.Up scanners provide the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software and hardware components of these scanners have been modified or improved in comparison to the predicate devices to support enhanced device functionality compared to the predicate devices. The hardware components of the subject device have been modified to include a Remote Scan Control (RSC) and a Control Device (Scan&GO) user interface (e.g. user interface via mobile tablet software application), modified gantry mechanics and patient tables, and a Stellar Technology detector.

Software version SOMARIS/10 syngo CT VA10A supports software features that are designed to enhance the user workflow such as, extended functionalities and GO technologies which provide interfaces to directly access optional post processing applications. The intended use and fundamental scientific technology for the SOMATOM go.Now and SOMATOM go.Up remains 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
- Iterative Reconstruction – Support of various iterative reconstruction methods
- 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
- High Power 80 (High mA @low kV)

The following technological differences exist between the subject device and predicate devices:

- Software version SOMARIS/10 syngo CT VA10A
- Chronon X-ray Tube
- 32 kW maximum power Generator
- Modified gantry that supports the integration of the ICS and IRS computers
- Support of additional cybersecurity features
- Support of workflow improvement features GO technologies
- Support of optional wired/wireless remote scan control module

- Support of interfaces to access optional post-processing applications

A tabular summary of the differences between the predicate and subject devices is provided as **Table 2** below:

Table 2: Comparison of Technological Characteristics

Property	Subject Device SOMATOM go.Up, SOMATOM go.Now	Primary Predicate Device SOMATOM Perspective (K142955)	Secondary Predicate Device SOMATOM Drive (K161196)	Secondary Predicate Device SOMATOM Scope (K142955)
Type of CT Scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner	whole body X-ray computed tomography scanner
System Hardware	continuously rotating tube detector system	continuously rotating tube detector system	two continuously rotating tube detector systems	continuously rotating tube detector system
	high voltage generator with max power 32kW	high voltage generator with max power 55kW	high voltage generator with max power 2x100kW	high voltage generator with max power 26kW
X-Ray Tube	Chronon	DURA 688/422	STRATON MX Sigma	DURA 352/202
kV Steps	80kV, 110kV,130kV	80kV, 110kV,130kV	70 kV, 80kV, 90kV, 100kV, 110kV, 120kV, 130kV, 140kV	80kV, 110kV,130kV
Selective Photon Shield	Tin Filter Technology	N/A	Tin Filter Technology	N/A
HMI & Gantry Display	realized as wireless tablet mobile medical application software, remote scan control (wired/wireless)	realized as buttons on both side of the gantry; touch display panel on gantry	realized as touch screen and buttons on both sides of the gantry	realized as buttons on both side of the gantry; one LCD display on gantry front
Operating System	Windows based SOMARIS/10 syngo CT VA10A	Windows based SOMARIS/5 syngo CT VC40	Windows based SOMARIS/7 syngo CT VA62A	Windows based SOMARIS/5 syngo CT VC40
Software	Basic Post Processing Viewer CT View&GO	Basic Post Processing provided by : syngo Viewing syngo Filming	Basic Post Processing provided by: syngo Viewing syngo Filming	Basic Post Processing provided by : syngo Viewing syngo Filming

<i>Property</i>	<i>Subject Device SOMATOM go.Up, SOMATOM go.Now</i>	<i>Primary Predicate Device SOMATOM Perspective (K142955)</i>	<i>Secondary Predicate Device SOMATOM Drive (K161196)</i>	<i>Secondary Predicate Device SOMATOM Scope (K142955)</i>
	Interface for Advanced Post Processing Application	Optional post processing and visualization applications accessed via a supported workstation	Optional post processing and visualization applications accessed via a supported workstation	Optional post processing and visualization applications accessed via a supported workstation
	Interface for Plugin (for future advanced visualization tools and extended functionalities)	Optional post processing and visualization applications accessed via a supported workstation	Optional post processing and visualization applications accessed via a supported workstation	Optional post processing and visualization applications accessed via a supported workstation
	Interface to support an optional mobile workflow control application software	Support of optional i-control interventional module that can be operated as a wired or Bluetooth connection based wireless table and gantry control module	Support of optional i-control interventional module that can be operated as a wired or Bluetooth connection based wireless table and gantry control module	N/A
	Image Reconstruction	Image Reconstruction	Image Reconstruction	Image Reconstruction
	IT Hardening	IT features supported that protect against cybersecurity attacks	IT Hardening	IT features supported that protect against cybersecurity attacks
	Data Exchange with external SW client (Teamplay) – allows to copy scan protocols from other systems	support of availability of scan protocols form other systems	Data Exchange with external SW client (Teamplay) – allows to copy scan protocols from other systems	support of availability of scan protocols form other systems
Iterative Reconstruction Methods	SAFIRE iMAR	SAFIRE iMAR	ADMIRE SAFIRE iMAR	SAFIRE iMAR

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 is completed. Test results show that the subject devices, the SOMATOM go.Now and SOMATOM go.Up, are comparable to the predicate devices

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

VII. Performance Data

Non Clinical Testing

Non-clinical test (integration and functional) including phantom tests were conducted for the SOMATOM go.Now and SOMATOM go.Up during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. Siemens claims conformance to the following performance standards: ISO 14791, NEMA XR-29, IEC 61223-2-6, IEC 61223-3-5, IEC 62304, NEMA XR-25, and DICOM 3.1-3.20.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the SOMATOM go.Now and SOMATOM go.Up in accordance with the following standards: IEC 60601-1, 60601-2-44, and 60601-1-2. Completed Form FDA 3654 are provided within this submission.

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 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 claim of substantial equivalence.

Siemens Healthcare 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 Remote Scan Control and Control Device (Scan&GO) which are options for SOMATOM go.Now and SOMATOM go.Up CT Systems complies to 47 CFR part 15 subpart c – Intentional Radiators. All Radio device labels will show an FCC ID code to show the compliance.

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 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 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 SOMATOM go.Now and SOMATOM go.Up should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM go.Now and SOMATOM go.Up scanners perform comparably to the predicate devices currently marketed for the same intended use. Since both devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM go.Now and SOMATOM go.Up testing supports a finding of substantial equivalence.