Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Blvd.
MALVERN PA 19355

April 13, 2018

Re: K173632
Trade/Device Name: SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Now, SOMATOM go.Up, and Scan&Go
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 15, 2018
Received: March 20, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K173632

Device Name

SOMATOM go.Up

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.

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. 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
SOMATOM go.Top

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.

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. 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
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.

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. 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
SOMATOM go.All

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.

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. 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 08/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
Scan&GO

Indications for Use *(Describe)*

The 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)

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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: March 15, 2018

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**
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
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

**Contact Person:**
Kimberly Mangum
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Phone: (610) 448-6477
Email: kimberly.mangum@siemens-healthineers.com

**II. Device Name and Classification**

| | |
|---|---|
| Product Name: | SOMATOM go.All |
| Propriety Trade Name: | SOMATOM go.All |
| 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 |

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| | |
|---|---|
| Product Name: | SOMATOM go.Top |
| Propriety Trade Name: | SOMATOM go.Top |
| 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.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 |

| | |
|---|---|
| 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:**

| | |
|---|---|
| Product Name: | SOMATON go.Now, SOMATOM go.Up |
| Propriety Trade Name: | SOMATON go.Now, SOMATOM go.Up |
| 510(k) Number: | K163296 |
| Clearance Date: | March 21, 2017 |
| 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 |

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| | |
|---|---|
| Primary Product Code: | JAK |
| Secondary Product Code: | LLZ |
| Recall Information: | All applicable recalls are considered and addressed as part of the design control process |

**Secondary Predicate Devices:**

| | |
|---|---|
| Product Name: | Scan&GO |
| Propriety Trade Name: | Scan&GO |
| 510(k) Number: | K163297 |
| Clearance Date: | March 24, 2017 |
| 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 |
| Recall Information: | There are currently no design related recalls for this device |

**IV. Device Description**

The SOMATOM go.Platform is comprised of the following 4 CT scanners and optional mobile workflow:

- SOMATOM go.Up
- SOMATOM go.Now
- SOMATOM go.Top
- SOMATOM go.All
- Scan&GO Mobile Medical Application (optional mobile workflow component)

The 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 above referenced CT 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 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 SOMATOM go.Platform CT scanners. Scan&GO can be operated on a Siemens provided tablet or a commercially available tablet that meets certain minimum technical requirements. It allows users to work in close proximity to the scanner and the patient. Specifically Scan&GO allows control/display of the following software interactions via a wireless tablet that meets certain minimum requirements:

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

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

The software version for the SOMATOM go.Platform, syngo CT VA20 (SOMARIS/10 syngo CT VA20), 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 VA20 is designed to provide a plugin interface to support the optional Scan&GO mobile workflow as well as integrate potential advanced post processing tasks, tools, or extendable functionalities. Software version syngo CT VA20 (SOMARIS/10 syngo CT VA20) is an update to software version syngo CT VA10A (SOMARIS/10 syngo CT VA20) which was cleared for the predicate devices, and supports the same plugin interfaces for the optional Scan&GO mobile workflow and integration of post-processing tasks as the predicate devices.

The SOMATOM go.Platform will support the following modifications/further developments in comparison to the predicate devices:

**Subject Device: SOMATOM go. Now and SOMATOM go.Up:** Modified from the primary predicate device SOMATOM go.Now and SOMATOM go.Up to support the following:

1) Modified Indication for Use Statement
2) New/Modified Hardware
   - Modified Patient Table
   - New Injector Arm (optional)
3) Software version SOMARIS/10 syngo CT VA20
   - Modified software to support CT Intervention from ICS console
   - Modified software to support CT Intervention as optional mobile workflow with Scan&GO
   - Modified Inline Vessel Ranges – Cardio CPR (curved planar reformation)
   - Modified Dynamic Serio Mode for perfusion
   - Modified basic post processing features
   - Modified HD FoV
4) Update 510(k) Information provided as Appendix H

**Subject Devices: SOMATOM go.All and SOMATOM go.Top Scanners:** Further developments of the primary predicate device SOMATOM go.Now and SOMATOM go.Up CT scanners including the following modifications:

1) New Marketing Name: SOMATOM go.All and SOMATOM go.Top
2) Modified Indications for Use Statement
3) New/Modified Hardware
   - Modified Patient Table
   - New Injector Arm (optional)
   - Modified Generator
   - Modified Stellar Detector
   - Modified X-Ray Tube
   - New Injector Arm (optional)
4) Software version SOMARIS/10 syngo CT VA20
   - Modified software to support CT Intervention from ICS console
   - Modified software to support CT Intervention as optional mobile workflow with Scan&GO
   - Modified Inline Vessel Ranges – Cardio CPR (curved planar reformation)
   - Modified Dynamic Serio Mode for perfusion
   - Modified basic post processing features
   - Modified HD FoV
   - Modified High Power 70
   - Modified CARE kV
   - Modified Adaptive Cardio Sequence
   - Support of TwinBeam Scan Mode (SOMATOM go.Top only)

- Support of Inline DE (Radial Ranges, Parallel Ranges) (SOMATOM go.Top only)

**Subject Device: Scan&GO Mobile Workflow (optional):** Further developments of mobile medical application software Scan&GO supported by SOMATOM go.Platform CT Scanner Systems including the following modifications:

1) Software version SOMARIS/10 syngo VA20
   - Optional new workflow - Guide&GO CT-Guided Intervention

A comparison of these modifications with respect to the predicate devices is provided in the "Comparison of Technological Characteristics with the Predicate Device" section below. As cleared in the predicate device, the subject device SOMATOM go.Now CT scanner is available in a 16 row 32 slice configuration and SOMATOM go.Up CT scanner is available in a 32 row 64 slice configuration. The configurations for the subject devices SOMATOM go.Now and SOMATOM go.Up will remain unchanged from the predicate device.

The subject device SOMATOM go.All scanner will be available in a 32 row 64 slice configuration and the SOMATOM go.Top scanner will be available in 64 row 128 slice configuration. A summary of the differences between the subject device CT scanner configurations is provided as **Table 1 and Table 2** below.

***Table 1:*** *SOMATOM go.Now and SOMATOM go.Up comparable properties*

| **Subject Device Comparison** | | |
|---|---|---|
| **Key specifications** | **SOMATOM go.Now** | **SOMATOM 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 | Not available | Available |
| Table Vertical Movement | Standard: No | Available |
| | 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 |
| Recon speed (images/s) | 9 (optional 13) | 13 |
| Detector width | 11.2 mm | 22.4 mm |
| Iterative Reconstruction Methods | SAFIRE, iMAR | SAFIRE, iMAR |
| Spiral Scan | Available | Available |

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**Table 2:** SOMATOM go.All and SOMATOM go.Top comparable properties

| Subject Device Comparison | | |
|---|---|---|
| **Key specifications** | **SOMATOM go.All** | **SOMATOM go.Top** |
| Physical Rows | 32 | 64 |
| Slice width (mm) | 0.7 | 0.6 |
| z coverage (mm) / Detector width | 22.4 | 38.4 |
| Rotation time (s) | 0.33, 0.5, 1.0 | 0.33, 0.5, 1.0 |
| FoV (cm) | 50 | 50 |
| Max scan range (cm) | 160 | 160 |
| Bore size (cm) | 70 | 70 |
| Gantry tilt | Available | Available |
| Table Vertical Movement | Available | Available |
| Table Load (kg) | Table Load: 227 | Table Load: 227 |
| | Optional: 300 | Optional: 300 |
| Power (kW) | 75 | 75 |
| XTA X-ray Tube | Athlon | Athlon |
| Tube heat capacity (MHU) | >=6 | >=6 |
| Iterative Reconstruction Control Unit | IRS-1c | IRS-1c |
| Iterative Reconstruction Methods | SAFIRE<br>iMAR | SAFIRE<br>iMAR |
| Spiral Scan | Available | Available |

**V. Indications for Use**

**SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All and SOMATOM go.Top:**

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. 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.

**Scan&GO:**

The 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

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**VI. Comparison of Technological Characteristics with the Predicate Device**
The SOMATOM go.Platform scanners and optional Scan&GO mobile workflow 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 the SOMATOM go.Platform have been modified or improved in comparison to the predicate devices to support enhanced device functionality when compared to the predicate devices.

Software version SOMARIS/10 syngo CT VA20 supports software features such as extended functionalities and GO technologies which provide interfaces to directly access optional post processing applications and are designed to enhance the user workflow. The intended use and fundamental scientific technology for the SOMATOM go.Platform 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
- Support of interfaces to access optional post-processing applications
- Patient table configurations
- Tin filtration technology
- Stellar detector technology
- High Power 80 (High mA@low kV)
- Support of optional wired/wireless Remote Scan Control (RSC)
- Support of the optional Scan &GO mobile workflow

**The following technological differences exist between the subject device SOMATOM go.Now and SOMATOM go.Up and the predicate device SOMATOM go.Now and SOMATOM go.Up:**

- Software version SOMARIS/10 syngo CT VA20
- New injector arm (optional)
- Support of Intervention Workflow for Scan&GO

**The following technological differences exist between the subject device SOMATOM go.All and SOMATOM go.Top and the predicate device SOMATOM go.Now and SOMATOM go.Up:**

- Software version SOMARIS/10 syngo CT VA20
- Athlon X-ray Tube
- Long scan range
- 75 kW maximum power Generator
- High Power 70
- New injector arm
- Software version SOMARIS/10 syngo CT VA20
- Support of Intervention Workflow for Scan&GO

**The following technological differences exist between the subject device Scan&GO and the predicate device Scan&GO:**

- Software version SOMARIS/10 syngo CT VA20

A tabular summary of the differences between the predicate and subject devices is provided as **Table 3**, **Table 4** and **Table 5** below:

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**Table 3:** Comparison of Technological Characteristics for SOMATOM go.Now and SOMATOM go.Up

| ***Property*** | ***Subject Device*** *SOMATOM go.Now* | ***Subject Device*** *SOMATOM go.Up* | ***Primary Predicate Device:*** *SOMATOM go.Now SOMATOM go.Up (K163296)* |
|---|---|---|---|
| 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 |
| System Hardware | continuously rotating tube detector system | continuously rotating tube detector system | continuously rotating tube detector system |
| | high voltage generator with max power 32kW | high voltage generator with max power 32kW | high voltage generator with max power 32kW |
| X-Ray Tube | Chronon | Chronon | Chronon |
| kV Steps | 80kV, 110kV,130kV | 80kV, 110kV,130kV | 80kV, 110kV,130kV |
| Selective Photon Shield | Tin Filter Technology | Tin Filter Technology | Tin Filter Technology |
| HMI & Gantry Display | realized as wireless tablet mobile medical application software, remote scan control (wired/wireless) | realized as wireless tablet mobile medical application software, remote scan control (wired/wireless) | realized as wireless tablet mobile medical application software, remote scan control (wired/wireless) |
| Software Operating System | Windows based | Windows based | Windows based |
| | SOMARIS/10 syngo CT VA20 | SOMARIS/10 syngo CT VA20 | SOMARIS/10 syngo CT VA10A |
| Software Features | Basic Post Processing Viewer | Basic Post Processing Viewer | Basic Post Processing Viewer |
| | Interface for Advanced Post Processing Application | Interface for Advanced Post Processing Application | Interface for Advanced Post Processing Application |
| | Interface for Plugin (for future advanced visualization tools and extended functionalities) | Interface for Plugin (for future advanced visualization tools and extended functionalities) | Interface for Plugin (for future advanced visualization tools and extended functionalities) |
| Software Features | Interface to support an optional mobile workflow control application software | Interface to support an optional mobile workflow control application software | Interface to support an optional mobile workflow control application software |
| | Image Reconstruction | Image Reconstruction | Image Reconstruction |
| | IT Hardening | IT Hardening | IT Hardening |

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| ***Property*** | ***Subject Device*** *SOMATOM go.Now* | ***Subject Device*** *SOMATOM go.Up* | ***Primary Predicate Device:*** *SOMATOM go.Now SOMATOM go.Up (K163296)* |
|---|---|---|---|
| Software Features | Data Exchange with external SW client (Teamplay) – allows to copy scan protocols from other systems | Data Exchange with external SW client (Teamplay) – allows to copy scan protocols from other systems | Data Exchange with external SW client (Teamplay) – allows to copy scan protocols from other systems |
| Iterative Reconstruction Methods | SAFIRE<br>iMAR | SAFIRE<br>iMAR | SAFIRE<br>iMAR |

**Table 4:** Comparison of Technological Characteristics for SOMATOM go.All and SOMATOM go.Top

| ***Property*** | ***Subject Device*** *SOMATOM go.All* | ***Subject Device*** *SOMATOM go.Top* | ***Primary Predicate Device*** *SOMATOM go.Now SOMATOM go.Up (K163296)* |
|---|---|---|---|
| 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 |
| System Hardware | continuously rotating tube detector system | continuously rotating tube detector system | continuously rotating tube detector system |
| | high voltage generator with max power 75kW | high voltage generator with max power 75kW | high voltage generator with max power 32kW |
| X-Ray Tube | Athlon | Athlon | Chronon |
| kV Steps | 70 kV / 80 kV / 90 kV / 100 kV / 110 kV / 120 kV / 130 kV / 140 kV | 70 kV / 80 kV / 90 kV / 100 kV / 110 kV / 120 kV / 130 kV / 140 kV | 80kV, 110kV,130kV |
| Selective Photon Shield | Tin Filter Technology | Tin Filter Technology | Tin Filter Technology |
| single source dual energy | N/A | Split Filter Technology (TwinBeam Dual Energy) | N/A |
| HMI & Gantry Display | realized as wireless tablet mobile medical application software, remote scan control (wired/wireless) | realized as wireless tablet mobile medical application software, remote scan control (wired/wireless) | realized as wireless tablet mobile medical application software, remote scan control (wired/wireless) |
| Software Operating System | Windows based<br>SOMARIS/10 syngo CT VA20 | Windows based<br>SOMARIS/10 syngo CT VA20 | Windows based<br>SOMARIS/10 syngo CT VA10A |

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| ***Property*** | ***Subject Device*** *SOMATOM go.All* | ***Subject Device*** *SOMATOM go.Top* | ***Primary Predicate Device*** *SOMATOM go.Now SOMATOM go.Up (K163296)* |
|---|---|---|---|
| Software Features | Basic Post Processing Viewer | Basic Post Processing Viewer | Basic Post Processing Viewer |
| | Interface for Advanced Post Processing Application | Interface for Advanced Post Processing Application | Interface for Advanced Post Processing Application |
| | Interface for Plugin (for future advanced visualization tools and extended functionalities) | Interface for Plugin (for future advanced visualization tools and extended functionalities) | Interface for Plugin (for future advanced visualization tools and extended functionalities) |
| | Interface to support an optional mobile workflow control application software | Interface to support an optional mobile workflow control application software | Interface to support an optional mobile workflow control application software |
| Software Features | Image Reconstruction | Image Reconstruction | Image Reconstruction |
| | IT Hardening | IT Hardening | IT Hardening |
| | Data Exchange with external SW client (Teamplay) – allows to copy or transfer scan protocols from / to other systems | Data Exchange with external SW client (Teamplay) – allows to copy or transfer scan protocols from / to other systems | Data Exchange with external SW client (Teamplay) – allows to copy scan protocols from other systems |
| Iterative Reconstruction Methods | SAFIRE<br>iMAR | SAFIRE<br>iMAR | SAFIRE<br>iMAR |

**Table 5**: Scan&GO Mobile Workflow

| **Technological Characteristic** | **SOMATOM go.Platform Scanner** | **SOMATOM go.Platform Scanner** |
|---|---|---|
| | Frontend:<br>Subject Device<br>**Scan&GO (VA20)** | Frontend:<br>Predicate Device<br>**Scan&GO (VA10)**<br>(K163297) |
| Software Operating Platform | Windows based SOMARIS/10 syngo CT VA20 operating software | Windows based SOMARIS/10 syngo CT VA10A operating software |
| Supported Hardware | Detached commercially available tablet that meets certain minimum requirements. | Detached commercially available tablet that meets certain minimum requirements. |
| Operating Software Platform | Windows 10 and .Net is required as operating platform | Windows 10 and .Net is required as operating platform |
| Connection to the scanner | Wi-Fi connection | Wi-Fi connection |

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| Technological Characteristic | SOMATOM go.Platform Scanner<br>Frontend:<br>Subject Device<br>**Scan&GO (VA20)** | SOMATOM go.Platform Scanner<br>Frontend:<br>Predicate Device<br>**Scan&GO (VA10)**<br>(K163297) |
|---|---|---|
| User Interface | Siemens delivers a tablet provided by external supplier as part of the respective SOMATOM go.Platform CT system. Alternatively, the application supports a commercially available tablet that meets certain minimum requirements. This has no specific modification compared to other commercially available tablet. | Siemens delivers a tablet provided by external supplier as part of the respective SOMATOM go. Platform CT system. Alternatively, the application supports a commercially available tablet that meets certain minimum requirements. This has no specific modification compared to other commercially available tablet. |
| Software Function | Scan parameter display | Scan parameter display |
| | Patient table position display | Patient table position display |
| | Tools and instruction message area | Tools and instruction message area |
| | Patient table position planning area | Patient table position planning area |
| | Physiological data display | Physiological data display |
| | Patient data display | Patient data display |
| | Information icons display | Information icons display |
| | display of acquired topogram and tomogram images | display of acquired topogram and tomogram images |
| | planning of tomogram scan | planning of tomogram scan |
| | finalization of exam | finalization of exam |
| | Selection of patients | Selection of patients |
| | Support of interventional workflow | N/A |
| | Selection of pre-defined protocols | Selection of pre-defined protocols |

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Siemens believes that the subject devices are substantially equivalent to the predicate devices. Testing and validation is completed. Test results show that the subject devices 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 subject devices during product development. The modifications described in this Premarket Notification are supported with verification and validation testing. Siemens attests 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, NEMA XR-28, AAMI/ANSI ES60601-1, IEC 62366.

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Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the subject devices in accordance with the following standards: IEC 60601-1, IEC 60601-2-44, IEC 60601-1-3, IEC 60601-1-6, and IEC 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 claims 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 the optional Remote Scan Control and supporting Control Device tablet 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 to IEC60601-2-44.

**Wireless Coexistence Testing**
Siemens has considered several measures to address wireless coexistence by design to ensure the safe operation of the wireless components in combination with the applicable system supported functionality. Wireless technology in the system setup to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules has been considered. According to FDA guidance 'Radio Frequency Wireless Technology in Medical Devices" Siemens has addressed the safety, effectiveness, and high likelihood of coexistence with other devices of this technology in our product design by our Risk Management Process, Failure Mode and Effects Analysis (FMEA) Process, and Requirement Engineering Process. As part of the risk management process, hazardous situations associated with the Scan&GO and its connection to the host system via Wi-Fi were addressed as part of the Risk Management process.

Testing for co-existence considered for following scenarios:

- Co-Channel Testing
- Adjacent Channel Testing
- RF Interference Testing
- Separation Distance/Location Testing

Scan&GO is designed to allow dynamic frequency selection and transmission power control by default in accordance with 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.

**Customer Use Testing**
The following clinical use testing was conducted to demonstrate Scan&GO's performance in the intended clinical environment:

- ***Internal Clinical Use Test***: The CT scanner customer environment is simulated in Siemens Test Cabins. For such a test, customers with clinical expertise are typically invited to perform tests.
- ***External Clinical Use Test:*** The CT scanner is tested in the environment of the clinic/hospital. Typically we perform these tests with selected customer before rollout of the CT scanner.

All test performed meet the pre-determined acceptance criteria and demonstrate that Scan&GO is safe and effective for the intended use.

**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.

A comparison of different technological characteristics and image quality metrics relevant to the task of lung scanner screening was performed for each new subject device. The results of these comparisons support the substantial equivalence for the new subject device CT scanners for the task of low dose CT lung cancer screening.

**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 devices are 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 SOMATOM go.Platform should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM go.Platform 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,

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Siemens believes that the data generated from the SOMATOM go.Platform testing supports a finding of substantial equivalence.