Siemens Medical Solutions USA, Inc
% Ms. Maria Ebio
Sr. Director, Regulatory Affairs
40 Liberty Blvd.
MALVERN PA 19355

June 27, 2019.

Re: K190578
Trade/Device Name: SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS Open, SOMATOM Edge Plus, SOMATOM Definition AS/AS+, SOMATOM Confidence
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 15, 2019
Received: May 16, 2019

Dear Ms. Ebio:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K190578

Device Name
SOMATOM Definition AS/AS+

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.*

*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.

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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)*
K190578

Device Name
SOMATOM Confidence

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.*

*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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# Indications for Use

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Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K190578

Device Name
SOMATOM Definition AS Open

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.*

*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
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# Indications for Use

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Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K190578

Device Name
SOMATOM Definition Edge

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.*

*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
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# Indications for Use

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Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K190578

Device Name
SOMATOM Definition Flash

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.*

*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)*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K190578

Device Name
SOMATOM Drive

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.*

*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
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# Indications for Use

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

510(k) Number *(if known)*
K190578

Device Name
SOMATOM Edge Plus

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.*

*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)*
K190578

Device Name
SOMATOM Force

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.*

*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)*

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K190578

# 510(K) SUMMARY
**FOR**
# SOMATOM CT SCANNER SYSTEMS – SOFTWARE VERSION SOMARIS/7 syngo CT VB20

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: February 28, 2019

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
Fax: (610) 640-4481
Email: kimberly.mangum@siemens.com

## II. Device Name and Classification

| | |
|---|---|
| Product Name: | SOMATOM Force |
| Trade Name: | SOMATOM Force |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Regulation Number: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

| | |
|---|---|
| Product Name: | SOMATOM Definition Flash |
| Trade Name: | SOMATOM Definition Flash |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Regulation Number: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

| | |
|---|---|
| Product Name: | SOMATOM Drive |
| Trade Name: | SOMATOM Drive |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Regulation Number: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

| | |
|---|---|
| Product Name: | SOMATOM Definition Edge |
| Trade Name: | SOMATOM Definition Edge |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Regulation Number: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

| | |
|---|---|
| Product Name: | SOMATOM Definition AS/AS+ |
| Trade Name: | SOMATOM Definition AS/AS+ |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Regulation Number: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

| | |
|---|---|
| Product Name: | SOMATOM Definition AS Open |
| Trade Name: | SOMATOM Definition AS Open |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Regulation Number: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

| | |
|---|---|
| Product Name: | SOMATOM Confidence |
| Trade Name: | SOMATOM Confidence |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Regulation Number: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

| | |
|---|---|
| Product Name: | SOMATOM Edge Plus |
| Trade Name: | SOMATOM Edge Plus |
| 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 CT Scanner Systems |
| 510(k) Number: | K173630 |
| Clearance Date: | March 30, 2018 |
| 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. |

**Predicate Device:**

| | |
|---|---|
| Trade Name: | SOMATOM Edge Plus |
| 510(k) Number: | K173607 |
| Clearance Date: | March 21, 2018 |
| 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: | There are currently no recalls for this device |

## IV. Device Description

Siemens intends to market a new software version, SOMARIS/7 syngo CT VB20 for the following SOMATOM Computed Tomography (CT) Scanner Systems:

**Dual Source CT Systems:**

- SOMATOM Force
- SOMATOM Drive
- SOMATOM Definition Flash

**Single Source CT Systems:**

- SOMATOM Definition AS/AS+
- SOMATOM Definition AS Open
- SOMATOM Definition Edge
- SOMATOM Confidence
- SOMATOM Edge Plus

The subject device SOMATOM CT Scanner Systems with SOMARIS/7 syngo CT VB20 are Computed Tomography X-ray Systems which feature one (single source) or two (dual source) continuously rotating tube-detector system and function according to the fan beam principle. The SOMATOM CT Scanner Systems with Software SOMARIS/7 syngo CT VB20 produces CT images in DICOM format, which 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 and therapy planning support (including, but not limited to, Brachytherapy, Particle including Proton Therapy, External Beam Radiation Therapy, Surgery). The computer system delivered with the CT scanner is able to run optional post processing applications.

The platform software for the SOMATOM CT Scanner Systems, SOMARIS/7 syngo CT VB20, is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The subject devices with software version SOMARIS/7 syngo CT VB20 will support the following modifications in comparison with the predicate devices:

**1) New/Modified Hardware**

- Table 1: Overview of Hardware modifications supported by software SOMARIS/7 syngo CT VB20

**2) Software version SOMARIS/7 syngo CT VB20**

- Table 2: Overview Software modifications of **Single Source CT** System Scanner with syngo CT VB20
- Table 3: Overview Software modifications of **Dual Source CT** System Scanner with syngo CT VB20

**3) Update 510(k) Information**

- Provided as Appendix H

***Table 1***: ***Hardware Modifications*** *Supported by software SOMARIS/7 syngo VB20*

| # | **SOMATOM CT System Scanner with SOMARIS/7 syngo CT VB20**<br><br>**hardware properties** | **Subject Devices** (Single Source Systems) | | **Subject Devices** (Dual Source Systems) | |
|---|---|---|---|---|---|
| | | • SOMATOM Definition AS/AS+;<br>• SOMATOM Definition AS Open; | • SOMATOM Definition Edge<br>• SOMATOM Confidence<br>• SOMATOM Edge Plus | • SOMATOM Force<br>SOMATOM Definition Flash | SOMATOM Drive |
| 1 | Stellar Detector (HW) | Unmodified | Modified | Unmodified | Modified |

***Table 2:*** *Overview* ***Software Modifications*** *of* ***Single Source CT*** *System Scanner with syngo CT VB20*

| # | **SOMATOM CT System Scanner with SOMARIS/7 syngo CT VB20 property** | **Single Source Subject Devices** | | |
|---|---|---|---|---|
| | | • SOMATOM Definition AS/AS+;<br>• SOMATOM Definition AS Open | SOMATOM Definition Edge | • SOMATOM Confidence;<br>• SOMATOM Edge Plus |
| 1 | Enhanced FAST DE Results | Modified | Modified | Modified |
| 2 | Precision Matrix | N/A | N/A | N/A |
| 3 | DirectBreathhold™ | New | New | New |
| 4 | IT Hardening | Modified | Modified | Modified |
| 5 | HD FoV (modification 4.0) | Modified | Modified | Modified |
| 6 | Extended i-Control Function | Enabled | Enabled | Enabled |
| 7 | Respiratory Scan Post-processing | Modified | Modified | Modified |
| 8 | Data Role Settings | Enabled | Enabled | Enabled |
| 9 | Stellar Detector (Firmware) | N/A | Modified | Modified |
| 10 | DirectDensity™ (showing relative mass density) | Modified | Modified | Modified |
| 11 | FAST 3D Camera | N/A | N/A | Modified |
| 12 | Support of Additional Dual Spiral Dual Energy Protocols | New | New | New |
| 13 | Modified User Interface Display | Modified | Modified | Modified |

***Table 3****: Overview* ***Software modifications*** *of* ***Dual Source CT*** *System Scanner with syngo CT VB20*

| # | **SOMATOM CT System Scanner with SOMARIS/7 syngo CT VB20 property** | **Subject Devices** (Dual Source) | | |
|---|---|---|---|---|
| | | SOMATOM Force | SOMATOM Drive | SOMATOM Definition Flash |
| 1 | Enhanced FAST DE Results | Modified | Modified | Modified |
| 2 | Precision Matrix | Modified | N/A | N/A |
| 3 | DirectBreathhold™ | N/A | New | New |
| 4 | IT Hardening | Modified | Modified | Modified |
| 5 | HD FoV (modification 4.0) | Unmodified | Modified | Modified |
| 6 | Extended i-Control Function | Enabled | Enabled | Enabled |
| 7 | Respiratory Scan Post-processing | N/A | Modified | Modified |
| 8 | Data Role Settings | Enabled | Enabled | Enabled |
| 9 | Stellar Detector (Firmware) | N/A | Modified | N/A |
| 10 | DirectDensity™ (showing relative mass density) | Modified | Modified | Modified |
| 11 | FAST 3D Camera | Modified | Modified | N/A |
| 12 | Support of Additional Dual Spiral Dual Energy Protocols | N/A | N/A | N/A |
| 13 | Modified User Interface Display | Modified | Modified | Modified |

A comparison of these modifications with respect to the predicate devices is provided the "**Comparison of Technological Characteristics with the Predicate Device**" section below. Software version SOMARIS/7 syngo CT VB20 will be offered as an optional upgrade for the applicable existing SOMATOM CT Systems.

## 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.
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.

## VI. Comparison of Technological Characteristics with the Predicate Device

The SOMATOM CT Scanner Systems with VB20 Software provide the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software features 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 devices have been modified to support a modified Stellar Technology detector.

Software version SOMARIS/7 syngo CT VB20 supports software features that are designed as Software Platform update including all new and modified features. The applicable features are depending on the SOMATOM CT Scanner Systems technological characteristics and are provided as optional features for updating the installed base and are designed features for the subject devices: SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS/AS+, SOMATOM AS Open, SOMATOM Confidence, SOMATOM Edge Plus which supporting the technological characteristics as Hardware precondition for its intended software usage.

The intended use and fundamental scientific technology for the SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS/AS+, SOMATOM AS Open, SOMATOM Confidence, SOMATOM Edge Plus 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

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

- Software version SOMARIS/7 syngo CT VB20
- Support of additional cybersecurity features
- Precision Matrix function
- Respiratory Scan – Functions
- i-Control Functions
- DirectDensity™ (showing relative mass density)

A tabular summary of the **unmodified** subject and predicate device comparable hardware properties is provided in **Table 4 and Table 5** below:

***Table 4: Unmodified*** *hardware properties valid for the subject device and predicate device*

| **Hardware Property** | **Subject and Predicate Device** (Single Source Systems) | | | | |
|---|---|---|---|---|---|
| | **SOMATOM Edge Plus** | **SOMATOM Definition Edge** | **SOMATOM Definition AS/AS+** | **SOMATOM Confidence** | **SOMATOM Definition AS Open** |
| **Scan mode** | single source, dual energy | | | | |
| **High voltage generator** | 100kW | | | | 80kW |
| **Detector** | 38.4mm (128 slice conf.) | | 19.2mm (20/40/64 slice conf.)<br>38.4mm (128 slice conf.) | 19.2mm | |
| **Detector Performance Technologie** | Stellar | | | | |
| **Tube** | STRATON MX Sigma | STRATON MX P | | | |
| **kV Steps** | 70kV,80kV,100kV, 120kV, 140kV | | | | |

***Table 5: Unmodified*** *hardware properties valid for the subject device and predicate device*

| **Hardware Property** | **Subject and Predicate Device** (Dual Source Systems) | | |
|---|---|---|---|
| | **SOMATOM Force** | **SOMATOM Definition Flash** | **SOMATOM Drive** |
| **Scan mode** | single source, dual source, dual energy | | |
| **High voltage generator** | 120kW/120kW | 100kW/100kW | |
| **Detector** | 2 x 57.6mm | 2 x 38.4mm | |
| **Detector Performance Technologie** | Stellar | | |
| **Tube** | Vectron | STRATON MX P | STRATON MX Sigma |
| **kV Steps** | 70kV,<br>80kV,<br>90kV, 100kV,<br>110 kV,<br>120 kV,<br>130 kV,<br>140 kV,<br>150 kV | 70kV,<br>80kV, 100kV,<br>120kV,<br>140kV | 70kV,<br>80kV,<br>90kV,<br>100kV,<br>110kV,<br>120kV,<br>130kV,<br>140kV |

The tabular summary of the **software and hardware differences** between the subject devices with software version SOMARIS/7 syngo CT VB20 and the predicate devices are listed in **Table 6 - Table 7** below (in gray shaded sections).

***Table 6:*** *Device Hardware Comparison for Subject (**Single Source** and **Dual Source CT System Scanner**) and Predicate Devices*

| **#** | **hardware properties** | **Subject Devices (syngo CT VB20)** | | **Predicate Device (K173630 / K173607)** |
|---|---|---|---|---|
| | | **Dual Source:**<br>• SOMATOM Force,<br>• SOMATOM Definition Flash<br><br>**Single Source**<br>• SOMATOM Definition AS/AS+<br>• SOMATOM Definition AS Open | **Dual Source:**<br>• SOMATOM Drive<br><br>**Single Source:**<br>• SOMATOM Definition Edge,<br>• SOMATOM Confidence<br>• SOMATOM Edge Plus | • Siemens SOMATOM CT Scanner System<br>• SOMATOM Edge Plus |
| 1 | Stellar Detector (HW) | Stellar Detector based on Sillian classic technologie supported | Stellar Detector based on **Sillian M technologie** supported | Stellar Detector based on Sillian classic technologie supported |

*Table 7: **Software** Comparison for Subject Devices (**Single Source and Dual Source CT Scanner System**) and Predicate Devices*

| ***Properties software*** | ***Subject Device*** | ***Predicate Device*** |
|---|---|---|
| | **Dual Source:**<br>• SOMATOM Force,<br>• SOMATOM Drive,<br>• SOMATOM Definition Flash<br>**Single Source:**<br>• SOMATOM Definition Edge,<br>• SOMATOM Definition AS/AS+,<br>• SOMATOM Definition AS Open,<br>• SOMATOM Confidence<br>• SOMATOM Edge Plus | • Siemens SOMATOM CT Scanner System (K173630)<br>• SOMATOM Edge Plus (K173607) |
| | **(syngo CT VB20)** | **(K173630 / K173607)** |
| Operating System | Windows based<br>SOMARIS/7 syngo CT VB20 | Windows based<br>SOMARIS/7 syngo CT VB10A |
| Acquisition Workplace | syngo Acquisition Workplace (AWP) | syngo Acquisition Workplace (AWP) |
| | optional 2nd console syngo RRWP | optional 2nd console syngo RRWP |
| | syngo Viewing, syngo Filming and syngo Archiving & Networking | syngo Viewing, syngo Filming and syngo Archiving & Networking |
| | Image Reconstruction | Image Reconstruction |
| Stellar Detector | Stellar detector firmware supported for subject device stellar detector re-design (no redesign for SOMATOM Force, Definition Flash and Definition AS Systems) | Stellar detector firmware supported for predicate device stellar detector design |
| Teamplay | Support teamplay Protocols | Support teamplay Protocols |
| Protocols (Single Source CT Scanner Systems) | Support of :<br>• Dual Spiral Dual Energy Protocols<br>• Protocols for Radiation Therapy Planning<br>• Dual Spiral Dual Energy Protocols for radiation therapy planning<br>• Protocols that allow triggering of breath hold scanning from external device. | Support of :<br>• Dual Spiral Dual Energy Protocols<br>• Protocols for Radiation Therapy Planning |
| Protocols (Dual Source CT Scanner Systems) | Support of :<br>• Protocols for Radiation Therapy Planning<br>• Protocols that allow triggering of breath hold scanning from external device. | Support of :<br>• Protocols for Radiation Therapy Planning |
| Cybersecurity | IT Hardening (improved) | IT Hardening |
| HD FoV | HD FoV (modification 4.0) | HD FoV 3.0 |
| Option for Patient Instructions. | Support Automatic Patient Instruction (API) Interface. | Support Automatic Patient Instruction (API) Interface. |
| FAST CARE | FAST, CARE Features supported | FAST, CARE Features supported |
| FAST DE Results | FAST DE Results with enhanced dialog box for individual image post-processing parameter settings and labeling | FAST DE Results |
| FAST Integrated Workflow* | FAST Integrated Workflow steps supported:<br>• FAST Isocentering<br>• FAST Range<br>• FAST Direction<br><br>*(full workflow only in combination with FAST 3D Camera) | FAST Integrated Workflow steps supported:<br>• FAST Isocentering<br>• FAST Range<br>• FAST Direction<br><br>*(full workflow only in combination with FAST 3D Camera) |
| FAST 3D Camera | FAST 3D Camera supported which provides more accurate proposals for | FAST 3D Camera supported which provides proposals for patient positioning and patient outline. |

| *Properties software* | ***Subject Device*** | ***Predicate Device*** |
|---|---|---|
| | **Dual Source:**<br>• SOMATOM Force,<br>• SOMATOM Drive,<br>• SOMATOM Definition Flash<br>**Single Source:**<br>• SOMATOM Definition Edge,<br>• SOMATOM Definition AS/AS+,<br>• SOMATOM Definition AS Open,<br>• SOMATOM Confidence<br>• SOMATOM Edge Plus | • Siemens SOMATOM CT Scanner System (K173630)<br>• SOMATOM Edge Plus (K173607) |
| | **(syngo CT VB20)** | **(K173630 / K173607)** |
| | patient positioning and patient outline. | |
| DirectDensity™ | DirectDensity™<br>(including electron density and mass density) | DirectDensity™<br>(including electron density) |
| Respiratory Scan Post-Processing | Respiratory Scan Post-Processing<br>Including automated transfer of t-MaxIP & t-MinIP series to DICOM node. | Respiratory Scan Post-Processing<br>Manual function for transferring t-MaxIP & t-MinIP series to DICOM node. |
| Precision Matrix (SOMATOM Force only) | Precision Matrix resolution<br>support image matrix sizes of 768x768 pixels and 1024x1024 pixel (auto mode supported) | Matrix resolution 512x512<br>(auto mode not supported) |
| breath-hold technique | DirectBreathholdTM (automated trigger supported)<br><br>(not for SOMATOM Force) | Respiratory Motion Management support breath hold triggered spiral scans with manual breath hold triggered examinations. |
| Extended i-Control Function | i-Control Function<br>(IVM support all key function's) | i-Control Function of 1st<br>(limited IVM key functions set) |
| Software | Support Auto Tasking card UI - with interactive settings of syngo.via Data Role | Support Auto Tasking card UI - showing selected syngo.via Data Role |
| User Interface | • Software Update: Smart Remote Service (SRS) or Anytime Software<br>• energy saving techniques in UI supported<br>• improved user doc | • Software Update: Smart Remote Service (SRS)<br>• limited energy saving techniques |
| Iterative Reconstruction Methods | • ADMIRE<br>• SAFIRE<br>• iMAR | • ADMIRE<br>• SAFIRE<br>• 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 CT Scanner Systems, 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 CT Scanner Systems during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the SOMATOM CT Scanner Systems in accordance with the following standards: 60601-2-44, and 60601-1-2. A list of recognized and general consensus standards considered for the subject devices is provided as **Table 8** and **Table 9** below.

| Table 8: Recognized Consensus Standards | | | | |
|---|---|---|---|---|
| **Date of Recognition** | **Recognition Number** | **Standard Developing Organization** | **Standard Designation Number and Date** | **Title of Standard** |
| 06/27/2016 | 12-300 | NEMA | PS 3.1 - 3.20 (2016) | Digital Imaging And Communications In Medicine (DICOM) Set |
| 03/14/2011 | 12-225 | NEMA | XR-25 | Computed Tomography Dose Check |
| 01/27/2015 | 12-287 | NEMA | XR-28 2013 | Supplemental Requirements For User Information And System Function Related To Dose In CT |
| 6/27/2016 | 5-40 | ANSI AAMI ISO | 14971:2007/(R)2010 (Corrected 4 October 2007) | Medical Devices - Applications Of Risk Management To Medical Devices |
| | | ISO | 14971 Second Edition 2007-03-01 | Medical Devices - Applications Of Risk Management To Medical Devices |
| 01/14/2019 | 13-79 | IEC | 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION | Medical Device Software - Software Life Cycle Processes |
| 07/09/2014 | 19-4 | ANSI AAMI | ES60601-1:2005/(R)2012 And A1:2012, | C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD) |
| 09/17/2018 | 19-8 | ANSI AAMI IEC | 60601-1-2:2014 | Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests*<br><br>*Existing SOMATOM Definition Flash systems conform to ANSI AAMI IEC 60601-1-2:2007. SOMATOM Definition Flash is no longer being manufactured or being delivered ex-factory. Software version SOMARIS/7 syngo CT VB20 supports updates of legacy SOMATOM Definition Flash scanner systems. |
| 7212/23/2016 | 5-114 | ANSI AAMI IEC | 62366-1:2015 | Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices |
| 07/09/2014 | 12-273 | IEC | 60825-1 Edition 2.0 2007-03 | Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)] |
| 06/27/2016 | 12-302 | IEC | 60601-2-44 Edition 3.2: 2016 | Medical Electrical Equipment - Part 2-44: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Computed Tomography |
| 01/14/2014 | 12-269 | IEC | 60601-1-3 Edition 2.1 2013-04 | Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment |
| 06/27/2016 | 5-89 | IEC | 60601-1-6 Edition 3.1 2013-10 | Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability |
| 03/14/2011 | 12-226 | IEC | 61223-2-6 Second Edition 2006-11 | Evaluation And Routine Testing In Medical Imaging Departments - Part 2-6: Constancy Tests - Imaging Performance Of Computed Tomography X-Ray Equipment |
| 01/30/2014 | 12-270 | IEC | 61223-3-5 First Edition 2004-08 | Evaluation And Routine Testing In Medical Imaging Departments - Part 3-5: Acceptance Tests |

| Table 8: Recognized Consensus Standards | | | | |
|---|---|---|---|---|
| **Date of Recognition** | **Recognition Number** | **Standard Developing Organization** | **Standard Designation Number and Date** | **Title of Standard** |
| | | | | - Imaging Performance Of Computed Tomography X-Ray Equipment [Including: Technical Corrigendum 1 (2006)] |
| 06/07/2018 | 12-309 | IEC | 60601-2-28 Edition 3.0 2017-06 | Medical Electrical Equipment - Part 2-28: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Tube Assemblies For Medical Diagnosis |
| 06/27/2016 | 12-299 | IEC | 62563-1 Edition 1.1 | Medical Electrical Equipment - Medical Image Display Systems - Part 1: Evaluation Methods |

| Table 9: General Use Consensus Standards | | | |
|---|---|---|---|
| **Standard Developing Organization** | **Standard Designation Number and Date** | **Title of Standard** | **How was Standard Used** |
| IEC | 60601-1-2:2007* | Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances – Requirements And Tests | This standard in not applicable for new Siemens CT scanners delivered ex-factory.<br><br>* Existing SOMATOM Definition Flash systems are conform to ANSI AAMI IEC 60601-1-2:2007. SOMATOM Definition Flash is no longer being manufactured or being delivered ex-factory. Software version SOMARIS/7 syngo CT VB20 supports updates of legacy SOMATOM Definition Flash scanner systems. |
| IEC | 60601-1:2005+A1:2012 | Medical electrical equipment - part 1: general requirements for basic safety and essential performance | Covered by ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 as part of EMC testing. |
| IEC/ISO | 17050-1 | Conformity Assessment – Supplier's declaration of conformity – Part 1: General requirements | Declaration of conformance to FDA recognized consensus standards. |
| IEC/ISO | 17050-2 | Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation. | General consensus standards not currently recognized by FDA. |

A list of applicable guidance documents considered for this submission is provided as **Table 10** below.

**Table 10:** FDA Guidance Documents

| FDA Guidance Document and Effective Date | |
|---|---|
| **1.** | Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k)**<br>Document issued on October 2, 2017 |
| **2.** | Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s**<br>Document issued on February 21, 2019 |
| **3.** | Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff**<br>Document issued on August 12, 2005 |
| **4.** | Guidance for Industry and FDA Staff: **Deciding when to submit a 510(k) for a change to an existing device.**<br>Document issued on October 25, 2017 |
| **5.** | Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]**<br>Document Issued on July 28, 2014 |

| FDA Guidance Document and Effective Date | |
|---|---|
| **6.** | Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices**<br>Document issued on May 11, 2005 |
| **7.** | Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices**<br>Document issued on September 9, 1999 |
| **8.** | Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices**.<br>Document issued February 3, 2016 |
| **9.** | Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications.**<br>Document issued on November 28, 2017 |
| **10.** | Guidance for Industry and FDA Staff: **Content of Premarket Submissions for Management of Cybersecurity in Medical devices.**<br>Document issued on October 2, 2014 |
| **11.** | Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices**<br>Document issued on July 11, 2016 |
| **12.** | Guidance for Industry and Food Drug Administration Staff: **Design considerations and Pre-Market Submission recommendations for Interoperable Medical devices**<br>Document Issued on September 6, 2017 |
| **13.** | Guidance for Industry and Food Drug Administration Staff:<br>**Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices**<br>Document issued on September 14, 2018 |

**Verification and Validation**

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. The 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 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**.**

**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 subject device SOMATOM CT Scanner Systems

should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM CT Scanner Systems 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 CT Scanner Systems testing supports a finding of substantial equivalence.