March 30, 2018

Siemens Medical Solutions USA, Inc.
Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Blvd.
Malvern, Pennsylvania 19355

Re: K173630
Trade/Device Name: SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS Open, SOMATOM Deinition 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: February 28, 2018
Received: March 14, 2018

Dear Kimberly 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 A. 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)*
K173630

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.

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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K173630

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)

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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K173630

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)

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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K173630

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)

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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K173630

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)

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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K173630

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)*

☒ 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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K173630

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)*

☒ 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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SIEMENS

510(K) SUMMARY
FOR
SOMATOM CT SCANNER SYSTEMS – SOFTWARE VERSION SOMARIS/7 syngo CT VB10

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: March 29, 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
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
Secondary Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Secondary CFR Section:	21CFR §892.2050
Device Class:	Class II
Product Code:	JAK

SIEMENS

Product Name:	SOMATOM Definition Flash
Trade Name:	SOMATOM Definition Flash
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:	21CFR §892.2050
Device Class:	Class II
Product Code:	JAK

Product Name:	SOMATOM Drive
Trade Name:	SOMATOM Drive
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:	21CFR §892.2050
Device Class:	Class II
Product Code:	JAK

Product Name:	SOMATOM Definition Edge
Trade Name:	SOMATOM Definition Edge
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:	21CFR §892.2050
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
Secondary Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Secondary CFR Section:	21CFR §892.2050
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
Secondary Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Secondary CFR Section:	21CFR §892.2050
Device Class:	Class II
Product Code:	JAK

Product Name:	SOMATOM Definition Confidence
Trade Name:	SOMATOM Definition Confidence
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:	21CFR §892.2050
Device Class:	Class II
Product Code:	JAK

SIEMENS

III. Predicate Device

Primary Predicate Device:

Trade Name:	SOMATOM Computed Tomography System Family Scanners
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:	This predicate has not been subject to a design-related recall

Predicate Device:

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

Predicate Device:

Trade Name:	SOMATOM Definition Edge
510(k) Number:	K143401
Clearance Date:	April 6, 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

Predicate Device:

Trade Name:	SOMATOM Force
510(k) Number:	K133589
Clearance Date:	April 17, 2014
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

Predicate Device:

Trade Name:	SOMATOM Definition Flash
510(k) Number:	K143416
Clearance Date:	April 16, 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

Predicate Device:

Trade Name:	SOMATOM Definition AS/AS+
510(k) Number:	K143400
Clearance Date:	April 8, 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

Predicate Device:

Trade Name:	SOMATOM Definition AS Open
510(k) Number:	K143409
Clearance Date:	March 26, 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

Predicate Device:

Trade Name:	SOMATOM Confidence
510(k) Number:	K162302
Clearance Date:	December 16, 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

IV. Device Description

Siemens intends to market a new software version, SOMARIS/7 syngo CT VB10 for the following SOMATOM Computed Tomography (CT) Scanner Systems:

Dual Source CT Systems:

- SOMATOM Force
- SOMATOM Drive
- SOMATOM Flash

Single Source CT Systems:

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

The subject device SOMATOM CT Scanner Systems with SOMARIS/7 syngo CT VB10 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 VB10 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 VB10, 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 VB10 will support the following modifications in comparison with the predicate devices:

1) **Modified Indications for Use Statement**
2) **New/Modified Hardware**
   - Table 1: Overview of Hardware modifications supported by software SOMARIS/7 syngo CT VB10
3) **Software version SOMARIS/7 syngo CT VB10**
   - Table 2: Overview Software modifications of **Dual Source CT** System Scanner with syngo CT VB10
   - Table 3: Overview Software modifications of **Single Source CT** System Scanner with syngo CT VB10
4) **Update 510(k) Information**
   - Provided as Appendix H

Table 1: Hardware Modifications Supported by software SOMARIS/7 syngo VB10

#	**SOMATOM CT System Scanner with SOMARIS/7 syngo CT VB10** **hardware properties**	**Subject Devices** (Dual Source)		**Subject Devices** (Single Source)		
		SOMATOM Force SOMATOM Drive	SOMATOM Flash	SOMATOM Definition Edge; SOMATOM Definition AS+	SOMATOM Definition AS; SOMATOM Definition AS Open	SOMATOM Confidence
1	3D Camera (in combination with Touch Display)	New	N/A	N/A	N/A	New
2	Extended Radiotherapy Functions	Modified	N/A	Modified	Modified	Modified
3	Tin Filter / Tin Filter Technologie	Unmodified	Enabled	Enabled	N/A	N/A

***Table 2**: Overview Software modifications of **Dual Source CT** System Scanner with software version SOMARIS/7 syngo CT VB10*

#	**SOMATOM CT System Scanner with SOMARIS/7 syngo CT VB10 property**	**Subject Devices** (Dual Source)		
		SOMATOM Force	SOMATOM Drive	SOMATOM Flash
1	HD FoV	Modified	Modified	Modified
2	kV and Filter Independent CaScore	Modified	Modified	Modified
3	FAST Topo	Modified	Modified	Modified
4	FAST Phase	Modified	Modified	Modified
5	IT Hardening	Enabled	Unmodified	Enabled
6	teamplay	Enabled	Unmodified	Enabled
7	syngo RRWP	Enabled	Unmodified	Unmodified
8	iMAR	Enabled	Unmodified	Unmodified
9	DirectDensity™	Enabled	Enabled	Enabled
10	Respiratory Motion Management	N/A	Modified	Modified
11	FAST 4D	N/A	Modified	Modified
12	Adaptive 4D Spiral (Sliding Gantry Mode)	N/A	N/A	N/A
13	Extended Radiotherapy Functions	Modified	Modified	N/A
14	FAST Integrated Workflow	New	New	N/A
15	FAST ECG Check	Enabled	Unmodified	N/A

Table 3: *Overview Software modifications of* ***Single Source CT*** *System Scanner with syngo CT VB10*

#	**SOMATOM CT System Scanner with SOMARIS/7 syngo CT VB10** **property**	**Subject Devices** (Single Source)			
		SOMATOM Definition Edge	SOMATOM Definition AS/AS+	SOMATOM Definition AS Open	SOMATOM Confidence
1	HD FoV	Modified	Modified	Modified	Modified
2	kV and Filter Independent CaScore	Modified	Modified	Modified	Modified
3	FAST Topo	Modified	Modified	Modified	Modified
4	FAST Phase	Modified	Modified	Modified	Modified
5	IT Hardening	Enabled	Enabled	Enabled	Unmodified
6	teamplay	Enabled	Enabled	Enabled	Unmodified
7	syngo RRWP	Unmodified	Unmodified	Unmodified	Unmodified
8	iMAR	Unmodified	Unmodified	Unmodified	Unmodified
9	DirectDensity™	Enabled	Enabled	Enabled	Unmodified
10	Respiratory Motion Management	Modified	Modified	Modified	Modified
11	FAST 4D	Modified	Modified	Modified	Modified
12	Adaptive 4D Spiral (Sliding Gantry Mode)	Modified	Modified	Modified	Modified
13	Extended Radiotherapy Functions	Modified	Modified	Modified	Modified
14	FAST Integrated Workflow	N/A	N/A	N/A	New
15	FAST ECG Check	N/A	N/A	N/A	Enabled

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 VB10 and the corresponding supported hardware 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 VB10 Software 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 devices have been modified to include features like 3D Camera Interface for topo positioning, tin filter, redesign of Interventional Module (IVM), gantry touch panels (GPA) user interface, modified gantry mechanics, patient tables, and a Stellar Technology detector.

Software version SOMARIS/7 syngo CT VB10 supports software features that are designed to support a new Software Platform 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

SIEMENS

Confidence 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 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 VB10
- Support of additional cybersecurity features
- Support of interfaces to access 3D Camera operation for fast patient positioning workflow
- DirectDensity™ Reconstruction, which provides CT images with an HU-like scaling that is nearly proportional to relative electron density
- Extended Radiotherapy Functions to support hardware and software interface options for RT

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

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

<table>
<tr><th rowspan="2">Hardware Property</th><th colspan="3">Subject and Predicate Device
(Dual Source Systems)</th><th colspan="4">Subject and Predicate Device
(Single Source Systems)</th></tr>
<tr><th>SOMATOM Force</th><th>SOMATOM Flash</th><th>SOMATOM Drive</th><th>SOMATOM Definition Edge</th><th>SOMATOM Definition AS/AS+</th><th>SOMATOM Confidence</th><th>SOMATOM Definition AS Open</th></tr>
<tr><td>Scan mode</td><td colspan="3">single source, dual source, dual energy</td><td colspan="4">single source, dual energy</td></tr>
<tr><td>High voltage generator</td><td>120kW*</td><td colspan="2">100kW/100kW</td><td colspan="3">100kW</td><td>80kW*</td></tr>
<tr><td>Detector</td><td>2 x 57,6 mm</td><td colspan="2">2 x 38.4 mm</td><td>38,4mm (128 slice conf.)</td><td>19,2mm (20/40/64 slice conf.)
38,4mm (128 slice conf.)</td><td colspan="2">19,2 mm</td></tr>
<tr><td>Tube</td><td>Vectron</td><td>STRATON MX P</td><td>STRATON MX Sigma</td><td colspan="4">STRATON MX P</td></tr>
<tr><td>kV Steps</td><td>70kV,
80kV,
90kV,
100kV,
110 kV,
120 kV,
130 kV,
140 kV,
150 kV</td><td>70kV,
80kV,
100kV,
120kV,
140kV</td><td>70kV,
80kV,
90kV,
100kV,
110kV,
120kV,
130kV,
140kV</td><td colspan="4">70kV,
80kV,
100kV,
120kV,
140kV</td></tr>
</table>

*(optional 100kW)

SIEMENS

The tabular summary of the software and hardware differences between the subject devices with software version SOMARIS/7 syngo CT VB10 and the predicate devices are listed in **Table 5 - Table 8** below.

Table 5: *Device Software Comparison for Subject (**Single Source CT System Scanner**) and Predicate Devices*

Software Property	***Subject Device*** *(Single Source)*	***Predicate Device*** *(Single Source)*		
	SOMATOM Definition Edge ***SOMATOM Definition AS/AS+,*** ***SOMATOM Definition AS Open,*** ***SOMATOM Confidence***	***SOMATOM Definition Edge*** ***SOMATOM Definition AS/AS+,***	***SOMATOM Definition AS Open***	***SOMATOM Confidence***
	syngo CT VB10	**(K143400) and (K143401)**	***(K143409)***	***(K162302)***
Operating System	Windows based SOMARIS/7 syngo CT VB10	Windows based SOMARIS/7 syngo CT VA48A	Windows based SOMARIS/7 syngo CT VA48A	Windows based SOMARIS/7 syngo CT VA62A
Software	syngo AWP	syngo AWP	syngo AWP	syngo AWP
	optional second operating console – syngo RRWP**	CTWP	CTWP	RRWP
	i-control & interventional module (redesign)	i-control & interventional module	i-control & interventional module	i-control & interventional module
	Image Reconstruction	Image Reconstruction	Image Reconstruction	Image Reconstruction
	IT Hardening	IT features supported that protect against cybersecurity attacks	IT features supported that protect against cybersecurity attacks	IT Hardening
	teamplay	support of availability of scan protocols form other systems	support of availability of scan protocols form other systems	teamplay
Iterative Reconstruction Methods	ADMIRE SAFIRE iMAR	ADMIRE SAFIRE iMAR	SAFIRE iMAR	ADMIRE SAFIRE iMAR
Sliding Gantry	Sliding Gantry configuration | syngo CT VB10,	Sliding Gantry configuration | syngo CT VA48A,	Sliding Gantry configuration | syngo CT VA48A,	Sliding Gantry configuration | syngo CT VA62A

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

Software Property	***Subject Device*** *(Dual Source)*	***Predicate Device*** *(Dual Source)*		
	SOMATOM Force ***SOMATOM Drive*** ***SOMATOM Definition Flash***	***SOMATOM Force***	***SOMATOM Definition Flash***	***SOMATOM Drive***
	syngo CT VB10	***K133589***	***K143416***	***K161196***
Operating System	Windows based SOMARIS/7 syngo CT VB10	Windows based SOMARIS/7 syngo CT VA50A	Windows based SOMARIS/7 syngo CT VA48A	Windows based SOMARIS/7 syngo CT VA62A
Software	AWP	syngo AWP	syngo AWP	AWP
	optional second operating console (syngo RRWP)	N/A	CTWP	optional second operating console (syngo RRWP)
	optional i-control IVM module (HW- redesign)	optional i-control IVM module	optional i-control IVM module	optional i-control IVM module
	Image Reconstruction	Image Reconstruction	Image Reconstruction	Image Reconstruction
	IT Hardening	IT features supported that protect against cybersecurity attacks	IT features supported that protect against cybersecurity attacks	IT Hardening
	teamplay	support of availability of scan protocols form other systems	support of availability of scan protocols form other systems	teamplay
Iterative Reconstruction Methods	ADMIRE SAFIRE iMAR	ADMIRE SAFIRE	ADMIRE SAFIRE iMAR	ADMIRE SAFIRE iMAR

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

Hardware Property	**Subject Devices (Single Source CT Scanner)**			**Predicate Devices (Single Source CT Scanner)**	
	SOMATOM Definition Edge, (syngo CT VB10)	**SOMATOM Confidence (syngo CT VB10)**	**SOMATOM Definition AS/AS+, SOMATOM Definition AS Open, (syngo CT VB10)**	**SOMATOM Definition Edge SOMATOM Definition AS/AS+, (K143401) (K143400) SOMATOM Definition AS Open (K143409)**	**SOMATOM Confidence (K162302)**
Selective Photon Shield	Tin Filter Technology	N/A	N/A	N/A	N/A
workflow for topogram scanning	conventional workflow	auto positioning for topo scan supported by 3D Camera	conventional workflow	conventional workflow	conventional workflow
Touch Display	N/A	on both sides of the gantry	N/A	N/A	on both sides of the gantry

Table 8: *Device Hardware Comparison for Subject (**Dual Source CT System Scanner**) and Predicate Devices*

Hardware Property	**Subject Device** (Dual Source CT Scanner)		**Predicate Devices** (Dual Source CT Scanner)		
	SOMATOM Force; SOMATOM Drive (syngo CT VB10)	**SOMATOM Definition Flash (syngo CT VB10)**	**SOMATOM Force K133589**	**SOMATOM Definition Flash K143416**	**SOMATOM Drive K161196**
Selective Photon Shield	Tin Filter Technology	Tin Filter Technology	Tin Filter Technology	N/A	Tin Filter Technology
workflow for topogram scanning	auto positioning for topo scan supported by 3D Camera	conventional workflow	conventional workflow	conventional workflow	conventional workflow
Touch Display	both sides of the gantry	N/A	N/A	N/A	both sides of the gantry

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. 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 CT Scanner Systems 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 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 in **Appendix E.**

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 both 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.