DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway, Mail Code D02
MALVERN PA 19355

November 24, 2015

Re: K142955
Trade/Device Name: Somatom Force, Somatom Definition Flash, Somatom Definition Edge, Somatom Definition AS/AS+, Somatom Definition AS Open, Somatom Definition, Somatom Emotion 16, Somatom Perspective 64/128, Somatom Perspective 64/32, Somatom Scope/Scope Power, SOMATOM Plus 4WITH Volume Zoom CT Scanners
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 30, 2015
Received: November 3, 2015

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142955

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.

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

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

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142955

Device Name
SOMATOM Definition AS/AS+

Indications for Use *(Describe)*

The Siemens SOMATOM Definition AS/ AS+ (Project P46) systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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510(k) Number *(if known)*
K142955

Device Name
SOMATOM Definition AS Open

Indications for Use *(Describe)*

The Siemens SOMATOM Definition AS Open systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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510(k) Number *(if known)*
K142955

Device Name
SOMATOM Definition Flash

Indications for Use *(Describe)*

The Siemens SOMATOM Definition Flash system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

In addition the SOMATOM Definition Flash is able to produce additional image planes and analysis results by executing optional post processing features, which operate on DICOM images.

The images and results delivered by the system can be used by a trained physician as an aid in diagnosis. (*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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510(k) Number *(if known)*
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Device Name
SOMATOM Definition Edge

Indications for Use *(Describe)*

The Siemens SOMATOM Definition Edge (Project P46F) systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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510(k) Number *(if known)*
K142955

Device Name
SOMATOM Definition

Indications for Use *(Describe)*

The SOMATOM P45 is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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510(k) Number *(if known)*
K142955

Device Name
SOMATOM Emotion 16

Indications for Use *(Describe)*

The SOMATOM Emotion 16 systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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See PRA Statement below.

510(k) Number *(if known)*
K142955

Device Name
SOMATOM Perspective 64/128

Indications for Use *(Describe)*

The Siemens SOMATOM Perspective 64/128 system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

In addition the SOMATOM Perspective is able to produce additional image planes and analysis results by executing optional post-processing features, which operate on DICOM images. For cardiac imaging, which is an option on the system, a new reconstruction algorithm (iTRIM - Iterative Temporal Resolution Improvement Method) is used. iTRIM improves the temporal resolution of cardiac CT images compared to conventional cardiac CT image reconstruction. Actual results obtained with iTRIM can vary depending on the particular clinical situation.

The images and results delivered by the SOMATOM Perspective can be used by a trained physician as an aid in diagnosis. (*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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510(k) Number *(if known)*
K142955

Device Name
SOMATOM Perspective 16/32

Indications for Use *(Describe)*

The Siemens SOMATOM Perspective 16/32 system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

In addition the SOMATOM Perspective is able to produce additional image planes and analysis results by executing optional post-processing features, which operate on DICOM images. For cardiac imaging, which is an option on the system, a new reconstruction algorithm (iTRIM - Iterative Temporal Resolution Improvement Method) is used. iTRIM improves the temporal resolution of cardiac CT images compared to conventional cardiac CT image reconstruction. Actual results obtained with iTRIM can vary depending on the particular clinical situation.

The images and results delivered by the SOMATOM Perspective can be used by a trained physician as an aid in diagnosis. (*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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510(k) Number *(if known)*
K142955

Device Name
SOMATOM Scope/Scope Power

Indications for Use *(Describe)*

The SOMATOM Scope and the SOMATOM Scope Power are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angels or spiral planes* taken at different angles.

The images and results delivered by the SOMATOM Scope and the SOMATOM Scope Power can be used by a trained physician as an aid in diagnosis.
(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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See PRA Statement below.

510(k) Number *(if known)*
K142955

Device Name

SOMATOM Plus 4WITH Volume Zoom CT Scanners

Indications for Use *(Describe)*

The Somatom Plus 4 with Volume Zoom package is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angels or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

*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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SIEMENS

510(K) SUMMARY
FOR
SOMATOM ( ) Computed Tomography System Family Scanners

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail code 65-1A
Malvern, PA 19355
Date Prepared: October 28, 2015

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.

1. General Information

Importer/Distributor:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail code: 65-1A
Malvern, PA 19355

Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG, MEDICAL SOLUTIONS
Siemensstrasse 1
91301 Forchheim, GERMANY

Establishment Registration Number:
3004977335

2. Contact Person:

Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
40 Liberty Boulevard, Mail Code 65-1A
Malvern, PA 19355
Phone: (610) 448-6477
Fax: (610) 640-4481
Email: kimberly.mangum@siemens.com

3. Device Name and Classification

Product Name:	SOMATOM Force
Propriety Trade Name:	SOMATOM Force
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

SIEMENS

Product Name:	SOMATOM Definition AS/AS+
Propriety Trade Name:	SOMATOM Definition AS/AS+
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Product Name:	SOMATOM Definition AS Open
Propriety Trade Name:	SOMATOM Definition AS Open
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Product Name:	SOMATOM Definition Flash
Propriety Trade Name:	SOMATOM Definition Flash
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Product Name:	SOMATOM Definition Edge
Propriety Trade Name:	SOMATOM Definition Edge
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Product Name:	SOMATOM Definition
Propriety Trade Name:	SOMATOM Definition
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Product Name:	SOMATOM Emotion 16
Propriety Trade Name:	SOMATOM Emotion 16
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Product Name:	SOMATOM Perspective 64/128
Propriety Trade Name:	SOMATOM Perspective
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology

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Classification Regulation:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Product Name:	SOMATOM Perspective 16/32
Propriety Trade Name:	SOMATOM Perspective
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Product Name:	SOMATOM Scope/Scope Power
Propriety Trade Name:	SOMATOM Scope/Scope Power
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Product Name:	SOMATOM Plus 4WITH Volume Zoom CT Scanners
Propriety Trade Name:	SOMATOM Plus 4WITH Volume Zoom CT Scanners
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Legally Marketed Predicate Devices

Trade Name:	SOMATOM Definition Force
510(k)#:	K133589
Clearance Date:	April 17, 2014
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Trade Name:	SOMATOM Definition AS/AS+
510(k)#:	K081022
Clearance Date:	June 02, 2008
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

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Trade Name:	SOMATOM Definition AS Open
510(k)#:	K130901
Clearance Date:	January 02, 2014
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Trade Name:	SOMATOM Definition Flash
510(k)#:	K121072
Clearance Date:	May 08, 2012
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Trade Name:	SOMATOM Definition Edge
510(k)#:	K120579
Clearance Date:	May 23, 2012
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Trade Name:	SOMATOM Definition
510(k)#:	K122471
Clearance Date:	September 11, 2012
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1750
Device Class:	II
Product Code:	90 JAK

Trade Name:	SOMATOM Emotion 16 CT System
510(k)#:	K133424
Clearance Date:	January 17, 2014
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Trade Name:	SOMATOM Perspective (128/64)
510(k)#:	K113287
Clearance Date:	May 23, 2012
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1750
Device Class:	Class II

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Product Code: 90JAK

Trade Name: SOMATOM Perspective (16/32)
510(k)#: K133590
Clearance Date: April 30, 2014
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1750
Device Class: Class II
Product Code: 90JAK

Trade Name: SOMATOM Scope/SOMATOM Scope Power
510(k)#: K140912
Clearance Date: September 15, 2014
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1750
Device Class: Class II
Product Code: 90JAK

Trade Name: SOMATOM Plus 4WITH Volume Zoom CT Scanners
510(k)#: K982349
Clearance Date: September 30, 1998
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1750
Device Class: Class II
Product Code: 90JAK

4. Substantial Equivalence:

The subject devices are unmodified compared to their recent cleared versions. As such the cleared versions as listed in **Table 1** below serve as the predicate devices:

Table 1: Predicate Device Comparable Properties

Predicate Devices	***FDA Clearance Number***	***FDA Clearance Date***
SOMATOM Force	K133589	April 17, 2014
SOMATOM Definition Flash	K121072	May 08, 2012
SOMATOM Definition Edge	K120579	May 23, 2012
SOMATOM Definition AS/AS+	K081022	June 02, 2008
SOMATOM Definition	K122471	September 11, 2012
SOMATOM Definition AS Open	K130901	January 02, 2014
SOMATOM Emotion 16 CT System	K133424	January 17, 2014
SOMATOM Perspective (32)	K133590	April 30, 2014
SOMATOM Perspective (64)	K113287	May 23, 2012
SOMATOM Scope/SOMATOM Scope Power	K140912	September 15, 2014
SOMATOM Plus 4WITH Volume	K982349	September 30,

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Predicate Devices	*FDA Clearance Number*	*FDA Clearance Date*
Zoom CT Scanners		1998

The following performance characteristics and image quality metrics relevant for low dose lung cancer screening were compared for the subject devices and the predicate devices, including predicate devices used as part of the NLST study.

- CT Number Accuracy
- CT Number Uniformity
- Spatial Resolution (MTF in-plane resolution)
- Slice Thickness/Sensitivity Profile (minimum slice width)
- Noise Properties
- Contrast to Noise Ratio
- Maximum Scan Speed
- Minimum Reconstructed Slice Interval
- Scan parameters for low dose lung cancer screening (as defined by publically available information including the NLST study)

5. Device Description:

Siemens SOMATOM Computed Tomography System family scanners are whole body X-ray computed tomography systems which feature a continuously rotating tube-detector system and functions according to the fan beam principle. The SOMATOM Computed Tomography System family scanners vary in configurations from 6 to 192 slices, and are intended to produce cross sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.

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 systems described in this submission provide pre-defined low dose scan modes similar to the modes used for The National Lung Screening Trial (NLST), and the features as recommend by the study. This allows use of these systems for screening in the same way the CT systems were used for NLST.

The computer system delivered with the CT scanner is able to run post processing applications optionally.

6. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

The SOMATOM Computed Tomography System family scanners referenced in this submission are comparable in indications for use, and are substantially equivalent in design, material, functionality, technology, energy source and are substantially equivalent to the predicate devices. No technical modifications have taken place to the subject device, and there are no technical differences between the predicate device and the subject device. The reason for this submission is to support the following additional Indications for Use:

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

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

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

*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.

This additional Indication for Use is based on the currently available technical parameters and software versions cleared for the predicate devices. The low dose lung cancer screening indication will be applicable for the Siemens qualified CT systems, and will not require any device modifications. Siemens predicate device systems included in this submission that received clearance after the Siemens system utilized as part of the NLST study have undergone modifications to improve performance, including but not limited to iterative reconstruction methods that support improved image quality and reduced dose. This indication will also be applicable for future qualified Siemens CT systems.

The intended use remains unchanged and the Indications for Use are similar. The technical parameters for general use CT such as minimum slice width, noise, Uniformity and mean value of CT numbers, maximum in-plane resolution of a non-UHR spiral scan mode, the minimum interval between two reconstructed images in axial direction and maximum scan speed are also applicable for lung cancer screening. A discussion of the specific image quality metrics assessed for the addition of this indication is provided in the performance testing section of this summary. The material, energy source, and fundamental scientific technology remain unchanged from the predicate devices; therefore Siemens believes that they are substantially equivalent to the predicate devices.

7. Nonclinical Testing:

The SOMATOM Computed Tomography System family scanners are designed to fulfill the requirements of following standards listed in **Table 2** below:

Table 2: Conformance Standards

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
2-156	Biocomp	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	10993-1:2009	01/15/2013	AAMI ANSI ISO
12-120	Radiology	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography - Ed. 2.1	60601-2-44 (2002-11):	09/09/2008	IEC
12-126	Radiology	Medical electrical equipment - Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis - Ed. 1.0	60601-2-28: 1993	10/31/2005	IEC

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Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
12-127	Radiology	Medical electrical equipment - Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment - Ed. 1.0	60601-2-32: 1994	10/31/2005	IEC
12-199	Radiology	Medical electrical equipment - Part 1-3: General requirements for basic safety 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment	60601-1-3 First edition 1994-07	09/08/2009	IEC
12-204	Radiology	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	60601-2-28 Edition 2.0 2010-03	08/05/2013	IEC
12-210	Radiology	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	60601-1-3 Edition 2.0 2008-01	08/05/2013	IEC
12-223	Radiology	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment CORRIGENDUM 1	61223-3-5 (First edition 2004)	03/18/2011	IEC
12-225	Radiology	Computed Tomography Dose Check	XR 25	03/18/2011	NEMA
12-226	Radiology	Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment	61223-2-6 Second Edition 2006-11	02/28/2011	IEC
12-238	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.18	03/16/2012	NEMA
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
5-27	General	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	60601-1-1:2000	09/08/2009	IEC
5-4	General	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995	60601-1	10/31/2005	IEC
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	08/20/2012	ISO

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Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
5-41	General	Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4:2000 Consol. Ed. 1.1	09/08/2009	IEC
5-54	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)	60601-1-2:2007	08/05/2013	AAMI ANSI IEC

Non clinical tests (integration and functional) and phantom testing were conducted for the SOMATOM Computed Tomography System family during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

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 was also provided for the systems referenced in this submission.

EMC/electrical safety was evaluated according to the IEC Standards. Siemens certify conformance to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. All testing and validation has been completed.

Performance Testing

Technical parameters utilized to test general CT use are also applicable for lung cancer screening. The following technical parameters have been compared for the subject devices and the Siemens devices used in NLST:

- CT number accuracy
- CT number uniformity
- Spatial resolution (MTF, maximum in-plane resolution)
- Slice thickness/sensitivity profile (minimum slice width)
- Noise properties
    - NPS
    - Image noise (standard deviation)
- Contrast to Noise Ratio
- (Maximum) scan speed
- Minimum reconstructed slice interval

The test results demonstrate that the subject devices perform comparably or better than the older devices. Since the older devices have been identified as suitable for lung cancer screening within the NLST, the respective performance of the subject devices can be regarded as suitable for lung cancer screening as well.

Reference Criteria and Clinical Literature

The evaluation criteria for lung cancer screening using Computed Tomography is a subset of the evaluation criteria for general chest CT. **Table 3** below provides a listing of criteria for chest CT for screening purposes and the applicable organizations assessed in support of Siemens Computed Scanners for low dose lung cancer screening:

Table 3: Chest CT Scanning Recommendations

Topic	General Chest CT	Chest CT for screening purpose	
	RSNA reporting template(RSNA 2015) and Fleischner criteria	Lung-RADs(Lung-RADS 2014) (criteria of ACR)	NCCN guideline(NCCN 2015)
Lung and large airways	e.g. pulmonary infiltrates, emphysema, abnormalities or the airways. **Evaluation of incidentally found pulmonary nodules explicitly outlined in the Fleischner criteria (MacMahon, Austin et al. 2005) : Nodules >4mm requiring follow-up, smaller nodules only in a high-risk patient**	Only focusing on pulmonary nodules. **New nodules >4mm require actions** (shortened follow-up period)	Focusing on pulmonary nodules, **new ground-glass nodules > 5mm require action** (shortened follow up)
Pleura	e.g. effusion, thickening	Not addressed	Not specifically addressed
Heart and pericardium	e.g. Size, pericardial effusion	Not addressed	Not specifically addressed
Mediastinum and hila	e.g. tumors, lymph nodes	Not addressed	Not specifically addressed
Chest wall and lower neck	e.g. thyroid, soft tissues	Not addressed	Not specifically addressed
Vessels	e.g. Atherosclerotic changes in aorta and coronaries	Not addressed	Not specifically addressed
Bones	e.g. fractures	Not addressed	Not specifically addressed

Clinical literature, including the findings of the National Lung Screening Trial (NLST), and technical guidelines for general chest CT such as American College of Radiology (ACR) and National Comprehensive Cancer Network (NCCN) were also used to support the feasibility of the use of Siemens Computed Tomography scanners for low dose lung cancer screening.

8. Intended Use Discussion:

In accordance with guidance document “Guidance for Industry. General/Specific Intended Use” issued November 4, 1998, and presentation “FDA/MITA Meeting on LDCT Lung Cancer Screening”, the modified more specific indication for use does not alter the intended use for the legally marketed predicate devices with a general

indication for use, nor does it alter the intended diagnostic effect in comparison to the predicate devices.

The following decision making criteria included in document “Guidance for Industry. General/Specific Intended Use” issued November 4, 1998 were assessed as part of this submission:

- Risk
- Public Health Impact
- Knowledge Base
- Endpoints
- Tool or Treatment
- Adjunctive Therapy
- Design Changes

Based on the results of the criteria above, Siemens computed tomography scanners are intended to produce cross sectional images of the body by computer reconstruction of x-ray transmission date. Lung cancer screening does not represent a new intended use

The more specific use of low dose lung cancer screening:

- Does not introduce new risk not normally associated with the general use of the device
- Does not impact public health to a significantly greater degree than the general diagnostic use of the device
- There is an extensive body of publically available evidence that reflects understanding by the medical community that use of CT for lung cancer screening is a subset of the general use rather than a new intended use
- The performance or clinical endpoints used to evaluate general CT use can also be applied to the specific use of lung cancer screening
- Does not perform any treatment functionality
- Does not require any other product not routinely needed for general CT to achieve the specific use safely or effectively
- Does not include any modifications to the general use CT device

The more specific use of low dose lung cancer screening is a subset of the general use, rather than a new intended use. As such, Siemens is of the opinion that the Intended Use/Indications for use are substantially equivalent to the predicate devices.

9. Indications for Use:

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

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

*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.

(See Indications for Use Statement for full Indications for Use Statements)

9. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence

In order to demonstrate substantial equivalence, the more specific indications for use low dose of lung cancer screening was assessed in accordance with guidance document "Guidance for Industry. General/Specific Intended Use" issued November 4, 1998, and presentation "FDA/MITA Meeting on LDCT Lung Cancer Screening", dated October 8, 2014. In accordance with these documents, it was determined that the modified more specific indication for use does not alter the intended use for the legally marketed predicate devices with a general indication for use, nor does it alter the intended diagnostic effect in comparison to the predicate devices.

In accordance with guidance document "Guidance for Industry. General/Specific Intended Use" issued November 4, 1998, it was determined that:

- The more specific indications for use of low dose lung cancer screening does not introduce risks not normally associated with the general use of the CT device, as the nature of CT, functionality, and performance has not been changed.

Based on Siemens evaluation of publically available information regarding the risk/benefits associated with the use of Computed tomography for lung cancer screening, Siemens is of the belief that the use of Siemens CT scanners for low dose lung cancer screening does not impact public health to a significantly greater degree than the general diagnostic use of the device, and falls within the general use of CT, as the criteria for low dose lung cancer screening is a subset of the criteria for general use CT.

- There is an extensive body of publically available evidence that reflects existing understanding by the medical community that the more specific use of CT for low dose lung cancer screening is a subset of the general use of CT, rather than a new intended use.

- Several general CT technical characteristics can also be used to define acceptable performance levels for use in lung cancer screening.

- The use of CT for low dose lung cancer screening is not intended to perform any treatment functions.

- There is no product not routinely needed for general CT required for use to safely or effectively perform the task of low dose lung cancer screening with CT.

- The use of CT for low dose lung cancer screening does not render the device less applicable to the diagnostic X-ray system tasks of general CT. The more specific use of low dose lung cancer screening is a subset of the general use, rather than a new intended use.

A comparison of the available protocol information for the Siemens CT predicate device utilized as part of the NLST study was also conducted, and the resulting information was provided within this submission to support the finding of substantial equivalence.

The predicate devices were cleared based on non-clinical supportive information and clinical images. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The comparison of technological characteristics, non-clinical performance data, and software validation demonstrates that the subject device is as safe and effective when compared to the predicate devices that are currently marketed for the same intended use.