



Food and Drug Administration
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August 24, 2016

Siemens Medical Solutions USA, Inc.
Kimberly Mangum
Regulatory Affairs Specialist
65 Valley Stream Parkway
Malvern, Pennsylvania 19355

Re: K161196

Trade/Device Name: SOMATOM Drive
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: July 22, 2016
Received: July 25, 2016

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.

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,

A handwritten signature in black ink, appearing to read 'R. Ochs', is written over a faint, large 'FDA' watermark.

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Indications for Use

510(k) Number (if known)

K161196

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.

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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510(k) Summary: **SOMATOM Drive**

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: July 20, 2016

This 510(k) summary of 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
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site

Siemens Healthcare GmbH
Siemensstrasse 1
D-91301 Forchheim, Germany
Establishment Registration Number: 3004977335

Contact Person:

Kimberly Mangum
Regulatory Affairs Specialist
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40 Liberty Boulevard
Malvern, PA 19355
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2. Device Name and Classification:

Product Name: SOMATOM Drive
Trade Name: SOMATOM Drive
Classification Name: Computed Tomography X-Ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

3. Legally Marketed Predicate Devices

Trade Name: SOMATOM Definition Flash
510(k) #: 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: This predicate device has not been the subject of any design related recalls.

Trade Name: SOMATOM Force, SOMATOM Definition Flash, SOMATOM Definition Edge, SOMATOM Definition AS/AS+, SOMATOM Definition AS Open, SOMATOM Emotion 6/16, SOMATOM Sensation 64/Sensation Cardiac , SOMATOM Perspective SOMATOM Scope/Scope Power

510(k) #: 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 device has not been the subject of any design related recalls

Reference Device

Trade Name: SOMATOM Force

510(k) #: 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: This reference device has not been the subject of any design related recalls

4. Device Description:

The Siemens SOMATOM Drive is a Computed Tomography X-ray System, which features two continuously rotating tube-detector systems and functions according to the fan beam principle. The SOMATOM Drive produces CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors. The computer system delivered with the CT scanner is able to run the post processing applications optionally. *syngo CT VA62A* (SOMARIS/7 VA62A) is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation available on the SOMATOM Drive CT system.

5. Indication 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.

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

The SOMATOM Drive provides the same technological characteristics in terms of materials, energy source and control mechanisms when compared to the predicate devices. The performance data of the X-ray tube and software features for the subject device SOMATOM Drive have been improved in comparison to the predicate device as described below:

X-Ray Tube/kV Steps Improvements:

The SOMATOM Drive includes two STRATON MX Sigma X-ray tubes, which are a modification of the X-ray tube to the predicate device (SOMATOM Definition Flash). This modification enables higher mA at lower kV levels, 70 kV and 80 kV (High Power 70 and High Power 80) in comparison to predicate device (SOMATOM Definition Flash).

The STRATON MX Sigma also enables consistent 10 kV steps from 70 to 140 kV, which were introduced as part of the predicate device (SOMATOM Force) and adds 90 kV, 110 kV and 130 kV steps in comparison to the predicate device (SOMATOM Definition Flash).

Tube Collimator Improvement

The SOMATOM Drive includes the Tin Filter (selective photon shield) as cleared in the predicate device (SOMATOM Definition Flash) on the collimator of both X-ray tubes, whereas the predicate device (SOMATOM Definition Flash) only had this on one X-ray tube.

Dual Power (full detector width)

The SOMATOM Drive allows the use of both tubes at the same kV with a routine pitch and full detector width, providing a doubling of the mA available in the examination (Dual Power Mode). The predicate device (SOMATOM Definition Flash) allows the use of both tubes at the same kV with a routine pitch only at half detector width.

Comparison of the technological characteristics

A tabular comparison of the technological characteristics between the subject device and predicate devices is provided as **Table 1** below:

Table 1: Subject Device Comparable Properties

Property	Subject Device: SOMATOM Drive	Primary Predicate Device: SOMATOM Definition Flash K143416	Secondary Predicate Device: SOMATOM Force cleared as part of K142955 and Reference Device K133589
Generator	high voltage generator with max power 100kW	high voltage generator with max power 100kW	high voltage generator with max power 120kW
User Interface	Touch based Human Machine Interface	LCD Front gantry display	LCD Front gantry display

Property	Subject Device: SOMATOM Drive	Primary Predicate Device: SOMATOM Definition Flash K143416	Secondary Predicate Device: SOMATOM Force cleared as part of K142955 and Reference Device K133589
Patient tables	standard patient table (PHS4n) OPTIONAL Multipurpose Table (MPT2n)	standard patient table (PHS4) OPTIONAL Multipurpose Table (MPT2)	standard patient table (PHS5) OPTIONAL Multipurpose Table (MPT4)
x-ray tube	STRATON MX Sigma	STRATON MX P	Vectron
kV Steps	70 kV, 80kV, 90kV, 100kV, 110kV, 120kV, 130kV, 140kV	70kV, 80kV, 100kV,120kV, 140kV	70kV, 80kV, 100kV, 120kV, 140kV
tube collimator	including movable tin filters for both tubes	including movable tin filters only for tube B	including movable tin filters for both tubes
Software	Windows based SOMARIS/7 VA62A	Windows based SOMARIS/7 VA48A	Windows based SOMARIS/7 VA50
Adjustable kV Settings	support of additional kV steps	Support of adjustable kV settings	Support of adjustable kV settings
Post-processing application Calcium Scoring	support for Calcium Scoring with SN 100kV tube power setting	Support of Calcium Scoring Post-Processing Application	Support of Calcium Scoring Post-Processing Application
iterative reconstruction methods	ADMIRE iMAR	SAFIRE ADMIRE iMAR	SAFIRE ADMIRE

The intended use and fundamental scientific technology remain unchanged from the predicate devices. The Indication for Use and technological characteristics are similar for the subject and predicate devices. Any differences in technological characteristics between the subject device and predicate devices do not raise different questions of safety and effectiveness. As such, Siemens believes that the subject device is substantially equivalent to the predicate devices.

7. Nonclinical Testing

The features described in this premarket notification are supported with verification and validation testing. Non clinical tests, including dosimetry and image performance, were conducted for the SOMATOM Drive 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.

Siemens claims conformance to the following standards: IEC 60601-1/A2: 2005; IEC 60601-2-44:2009 +A1:2012; XR-29: 2013; ISO/IEC 14971:2007; IEC 62304: Ed. 1.0 2006, IEC 61223-2-6: 2006, 61223-3-5: 2004, XR 25, ISO/IEC 10918-1: 1994, DICOM NEMA PS 3.1 – PS 3.20.

The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional), including phantom test were conducted during the SOMATOM Drive 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.

Additional provided supporting data

The National Lung Screening Trial (NLST), sponsored by the National Cancer Institute, is used to support the additional lung cancer screening Indications for Use. The study was a randomized trial of screening with the use of low-dose CT compared to chest radiography to determine whether screening with low-dose CT could reduce mortality from lung cancer. The study start date was August, 2002 and the completion date was October, 2010. The interpretation task with CT for this study was to detect lung nodules of 4mm diameter or greater.

8. Clinical Testing

Clinical images were evaluated to demonstrate performance for Dual Source Dual Power mode. Clinical experience phrased in peer reviewed articles support the performance and effectiveness of several features provided with SOMATOM Drive.

9. 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 hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. In order to minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence:

The subject device non-clinical data similarly supports the safety of the software with verification and validation testing. Verification and validation testing demonstrates that the SOMATOM Drive performs as intended. The non-clinical test data demonstrates that the SOMATOM Drive performance is comparable to the predicate devices that are currently marketed for the same intended use.

For SOMATOM Drive, Siemens used the same testing with the same workflows as was used to clear the predicate devices. Since both devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM Drive testing supports a finding of substantial equivalence.