K130901

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JAN - 2 2014

510(K) SUMMARY
FOR
SOMATOM DEFINITION AS OPEN

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: December 4, 2013

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.
51 Valley Stream Parkway
Malvern PA, 19355

Establishment Registration Number:
2240869

Manufacturing Site:
Siemens AG, Medical Solutions
Siemensstrasse 1
Forchheim, Germany 91301

Establishment Registration Number:
3004977335

2. **Contact Person:**
Ms. Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 448-1772 Fax: (610) 448-1778
Email: kimberly.mangum@siemens.com

3. **Device Name and Classification**

Product Name:	SOMATOM Definition AS Open
Propriety Trade Name:	SOMATOM Definition AS Open
Classification Name:	Computed Tomography X-ray System

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Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Legally Marketed Predicate Device

Trade Name:	SOMATOM Definition AS Open
510(k)#:	K103127
Clearance Date:	March 04, 2011
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1750
Device Class:	II
Product Code:	JAK

4. **Device Description:**

The Siemens SOMATOM Definition AS Open is a whole body X-ray Computed Tomography System. The SOMATOM Definition AS Open produces CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors.

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 new version of system software, *syngo® CT 2013B* (SOMARIS/7 VA46A), supports the following features:

- **MARIS (Metal Artifact Reduction in Image Space)** – A image reconstruction mode designed to reduce image artifacts caused by metal
- **HD FoV Pro (HD FoV 2.0)** – Designed to enable a more reliable visualization of the skin line of human body parts located outside of the standard field of view
- **t-MIP** – Image manipulation method for arithmetic operations which allows the calculation of temporal Maximum or Minimum Intensity Projection (MIP) images from a set of series.

5. **Indications for Use:**

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 resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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6. **Substantial Equivalence:**
Siemens SOMATOM Definition AS Open configured with software version syngo® CT 2013B (Somaris/7 VA46A) is substantially equivalent to the following medical devices in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens Definition AS Open	K103127	03/04/2011
Siemens SOMATOM Definition Edge	K120579	05/23/2012

7. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**
SOMATOM Definition AS Open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) is a further software development to the commercially available SOMATOM Definition AS Open CT system.

The SOMATOM Definition AS Open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) features the same indications for use, gantry, imaging and administrative functions as the predicate SOMATOM Definition AS Open. The image reconstruction and image manipulation are similar to the predicate device SOMATOM Definition AS Open.

The difference between the legally marketed predicate device SOMATOM Definition AS Open and the SOMATOM Definition AS Open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) is as follows:

Property	**SOMATOM Definition AS Open (configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A)**	**SOMATOM Definition AS Open**
Image reconstruction method for artifact reduction	MARIS – Reduces metal artifacts	Posterior Fossa Optimization (PFO) reduces beam hardening artifacts
Reconstructed Field of View	HD FoV Pro (HD FoV 2.0) – Allows visualization of up to 80 cm	HD FoV – Allows visualization of up to 78 cm
3D display	tMIP – Allows calculation of temporal maximum intensity projection images	MIP – Allows calculation of maximum intensity projection images

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The SOMATOM Definition AS Open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) does not have significant changes in materials, energy source, or technological characteristics when compared to the predicate devices. The intended use and fundamental scientific technology are similar to the predicate devices; therefore Siemens believes that they are substantially equivalent to the predicate devices.

8. **Nonclinical Testing:**

SOMATOM Definition AS Open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) is designed to fulfill the requirements of following standards:

- IEC 60601-1-4 : 2000; Medical electrical equipment - Part 1-4: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical Devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: NEMA PS 3.1 – 3.18 (2009)
- IEC 60601-2-44:2009; Medical Electrical Equipment Part 2: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
- IEC 61223-3-5:2004; Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment CORRIGENDUM 1
- IEC 61223-2-6:2006; Evaluation and routine testing in medical imaging departments – Part 2 – 6: Constancy tests – Imaging performance of computed tomography X-ray equipment

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) and phantom were conducted on the SOMATOM Definition AS Open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) during software development. Additionally, bench tests were performed to verify and validate the performance of the MARIS and HD FoV Pro (HD FoV 2.0) features.

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 of the device was found acceptable to support the claims of substantial equivalence.

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.

9. Clinical Testing

Clinical test were performed using the SOMATOM Definition AS Open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) to validate the performance of the MARIS algorithm. These tests include testing of the metal artifact reduction capabilities of MARIS in different clinical scenarios.

10. 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.

11. Conclusion as to Substantial Equivalence

In summary, Siemens is of the opinion that the SOMATOM Definition AS open configured with software version *syngo® CT 2013B* (SOMARIS/7 VA46A) software package does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.

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

January 2, 2014

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

Re: K130901
Trade/Device Name: SOMATOM Definition AS Open
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 13, 2013
Received: December 23, 2013

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.

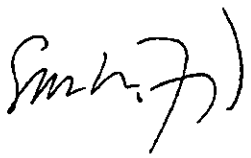
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130901

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 resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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