



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

Siemens Medical Solutions USA, Inc.  
% Ms. Eve Davis  
Regulatory Affairs Specialist  
51 Valley Stream Parkway  
MALVERN PA 19355

March 26, 2015

Re: K143409  
Trade/Device Name: SOMATOM Definition AS Open (VA48)  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: February 20, 2015  
Received: February 23, 2015

Dear Ms. Davis:

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 that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

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

Enclosure

## Indications for Use

510(k) Number (if known)  
K143409

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)

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.\***

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## 510(k) Summary: SOMATOM Definition AS Open

**Company:** Siemens Medical Systems USA, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355

**Date Prepared:** February 12, 2015

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.  
51 Valley Stream Parkway  
Malvern, PA 19355

**Establishment Registration Number:** 2240869

**Location of Manufacturing Site**

**SIEMENS AG Healthcare**

Siemensstrasse 1  
D-91301 Forchheim, Germany

**Establishment Registration Number:** 3004977335

**2. Contact Person:**

Eve Davis  
Regulatory Affairs Specialist  
Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway, D-02  
Malvern, PA 19355  
Phone: (610) 219-7133 Fax: (610) 448-1787  
Email: eve.davis@siemens.com

**3. Device Name and Classification:**

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

**4. Legally Marketed Predicate Device**

**Trade Name:** SOMATOM Definition AS Open (VA46)  
**510(k) #:** K130901  
**Clearance Date:** January 2, 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 predicate device has not been the subject of any design related recalls.

**5. Device Description:**

New software version *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation that will be available on the SOMATOM Definition AS Open Computed Tomography systems. *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) is a further development to the SOMARIS/7 operating software cleared as part of the predicate device.

*syngo*<sup>®</sup> VA48 is scanner platform software that supports the following device features:

**1). New system scanner software version *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) which includes:**

- Respiratory – Analysis of Respiratory Rate & Pitch Adjustment
- FAST 3D Reconstruction (FAST 3D Align)
- Multiphase reconstruction with extended Field of View
- FAST DE Results (Dual Energy PACS-ready images)
- FAST contact
- Iterative Reconstruction with extended Field of View
- OEM Varian RGSC Online Mode
- Full 4D Lung Scan
- Applications at CT - *syngo.via* client
- TrueD 4D Viewer

**2). ADMIRE Iterative Reconstruction (Option)**

**3). iMAR Improved Metal Artifact Reduction (Option)**

There are no modifications to the hardware of the device.

**6. Indication 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.)

**7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**

The SOMATOM Definition AS Open configured with software version *syngo*<sup>®</sup> VA48 does not have significant changes in materials, energy source, or technological characteristics when compared to the predicate device. Both the subject device and predicate device are computed tomography scanners that support various visualization and evaluation tools. The intended use and fundamental scientific technology are similar to the predicate device. The table below provides a comparison of the primary features of the subject device in comparison to the predicate device.

## Subject and Predicate Device Compared Technological Characteristics

Subject Device Feature	Predicate Device Feature
New system scanner software version <i>syngo</i> <sup>®</sup> VA48 (SOMARIS/7 VA48) with supported software options	System scanner software <i>syngo</i> <sup>®</sup> VA44 (SOMARIS/7 VA44) with supported software options
New Iterative Reconstruction ADMIRE (option)	Iterative Reconstruction SAIRE (option)
iMAR Iterative Metal Artifact Reduction (option)	MARIS Metal Artifact Reduction (option)

### 8. Nonclinical Testing

SOMATOM Definition AS/AS+ configured with software version *syngo*<sup>®</sup> VA48 is designed to fulfill the requirements of the following standards:

- IEC 60601-2-44: Medical electrical equipment – Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography – Ed. 2.1
- IEC 61223-3-5: Evaluation and routine testing Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment CORRIGENDUM 1
- NEMA XR-25: Computed Tomography Dose Check
- IEC 61223-2-6: Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment
- NEMA PS 3.1 – 3.18: Digital Imaging and Communications in Medicine (DICOM) Set
- IEC 62304 Ed. 1.0: Medical device software – software life cycle processes
- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for Safety, 1988, Amendment 1, 1991-11, Amendment 2, 1995
- ISO 14971: Medical devices – Application of risk management to medical devices
- NEMA XR-29: Standard Attributes on CT Equipment Related to Dose Optimization and Management
- ISO/IEC 10918-1: Digital Compression and Coding of Continuous-Tone Still Images (JPEG); 1994-02

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

### Software 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.

Non-clinical tests (integration and functional) were conducted during the SOMATOM Definition Flash product development. The performance data demonstrates continued conformance with special controls for medical devices containing software.

**Summary**

Performance tests were conducted to test the functionality of the SOMATOM Definition AS Open configured with software version *syngo*<sup>®</sup> VA48. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

**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 and 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:**

The predicate device was cleared based on non-clinical data as specified by recognized standards. Non-clinical data for the subject device was also gathered in this way. The SOMATOM Definition AS Open configured with software version *syngo*<sup>®</sup> VA48 has the same intended use and indication for use as the predicate device.

The non-clinical data support the safety of the device and the software verification and validation demonstrate that the SOMATOM Definition AS Open configured with software version *syngo*<sup>®</sup> SOMARIS/7 VA48 should perform as intended in the specified use conditions.