



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

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

April 6, 2015

Re: K143401  
Trade/Device Name: SOMATOM Definition Edge  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: February 10, 2015  
Received: February 13, 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,

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

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)  
K143401

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 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(K) SUMMARY  
FOR  
SOMATOM Definition Edge Computed Tomography Systems**

Submitted by:  
Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355  
Date Prepared: January 29, 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 Establishment:**

Registration Number: 2240869  
Siemens Medical Solutions, Inc.  
51 Valley Stream Pkwy  
Malvern, PA 19355

**Manufacturing Facility:**

Siemens AG; Medical Solutions  
Siemensstrasse 1  
91301 Forchheim, GERMANY

**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) 448-4912  
Fax: (610) 448-1787  
Email: kimberly.mangum@siemens.com

**3. Device Name and Classification**

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

**4. Legally Marketed Primary Predicate Device:**

**Product Name:** SOMATOM Definition Edge

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

**Legally Marketed Secondary Predicate Device:**  
**Name:** SOMATOM Definition AS Open  
**Propriety Trade Name:** SOMATOM Definition AS Open  
**Classification Name:** Computed Tomography X-ray System  
**Classification Panel:** Radiology  
**CFR Section:** 21 CFR §892.1750  
**Device Class:** Class II  
**Product Code:** 90 JAK

## 5. Indications for Use

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

## 6. Substantial Equivalence:

Siemens SOMATOM Definition Edge Computed Tomography Systems with software version *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) is substantially equivalent to the following medical devices in commercial distribution as listed in **Table 1**:

**Table 1:** Predicate Devices

<b>Manufacturer</b>	<b>Predicate Device</b>	<b>510(k) #</b>	<b>Clearance Date</b>
Siemens	SOMATOM Definition Edge	K120579	May 23, 2012
<b>Manufacturer</b>	<b>Secondary Device</b>	<b>510(k) #</b>	<b>Clearance Date</b>
Siemens	SOMATOM Definition AS Open	K130901	January 2, 2014

## 7. Device Description:

Siemens intends to market a new software version, *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) for its SOMATOM Definition Edge Computed Tomography X-ray systems. The subject device SOMATOM Definition Edge will be delivered with software version *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48). Additionally software version *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) will be offered as an optional upgrade for existing SOMATOM Definition Edge systems. *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) is a further development to the SOMARIS/7 operating software cleared as part of the predicate devices. A listing of device modifications is as follows:

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1. New software version *syngo*<sup>®</sup> VA48 (SOMARIS/7 VA48) to support the following additional features:
  - TwinBeam Scanning
  - Adaptive Spiral (zig-zag scan) for Sliding Gantry Configuration
  - Respiratory - Analysis of Respiratory Rate & Pitch Adjustment
  - FAST 3D Reconstruction (Auto 3D Recon 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
  - Temporal MIP (t-MIP)
  - TrueD 4D Viewer
  - HD Field of View Pro (HD FoV 2.0)
2. ADMIRE Iterative Reconstruction (option)
3. iMAR Improved Metal Artifact Correction (option)
4. MARIS (Metal Artifact Reduction in Image Space) Option
5. HandCARE Quantitative Dose Reduction Option
6. CARE Dose4D Dose Reduction Option

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

SOMATOM Definition Edge 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 devices. Both the subject device and predicate devices are computed tomography scanners that support various visualization and evaluation tools. 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. **Table 2** below provides a comparison of the primary features of the subject device in comparison to the predicate device.

**Table 2:** Predicate Device Comparison

Subject Device Feature	Predicate Device Comparable Feature
New 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
ADMIRE Iterative Reconstruction (option)	Optional Iterative Reconstruction (option)
iMAR Iterative Reconstruction (option)	Optional Iterative Reconstruction (option)
MARIS (option)	MARIS (option)
HandCARE with Quantitative Dose	HandCARE with Quantitative Dose

Subject Device Feature	Predicate Device Comparable Feature
Reduction Option	Reduction Option
CARE Dose4D Quantitative Dose Reduction Option	CARE Dose4D Quantitative Dose Reduction Option

## 9. Nonclinical Testing:

SOMATOM Definition Edge 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

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests were conducted for the SOMATOM Definition Edge configured with software version *syngo*<sup>®</sup> VA48 during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

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 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.

### **Summary**

Performance tests were conducted to test the functionality of the SOMATOM Definition Edge 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.

### **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:**

The SOMATOM Definition Edge configured with software version *syngo*<sup>®</sup> VA48 has the same intended use and comparable indication for use as the predicate devices. The technological characteristics such as image acquisition, operating platform, and image manipulation are similar to the predicate devices

The predicate devices were cleared based on non-clinical supportive information and clinical images. The results of these tests demonstrate that the SOMATOM Definition Edge (K120579) and SOMATOM Definition AS Open (K130901) 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.