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.
% Mr. John Urtz
Regulatory Affairs Specialist
40 Liberty Boulevard, Mail Code 65-1A
MALVERN PA 19355

November 12, 2015

Re: K151752
Trade/Device Name: SOMATOM Emotion 6/16
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 23, 2015
Received: October 23, 2015

Dear Mr. Urtz:

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, 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)*
K151752

Device Name
SOMATOM Emotion 6/16

Indications for Use *(Describe)*
SOMATOM Emotion 6/16 CT 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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740

510(K) SUMMARY

FOR

SOMATOM Emotion 6/16 Systems

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

November 9, 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.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Manufacturing Facility (1):
SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD
278 Zhou Zhu Rd
Shanghai, CHINA, 201318
Establishment Registration Number:
3003202425

Manufacturing Facility (2):
Siemens AG; Medical Solutions
Siemensstrasse 1
91301 Forchheim, GERMANY
Establishment Registration Number:
3004977335

2. Contact Person:

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Regulatory Affairs Specialist
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40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355-1406
Phone: (610) 448-6002 Fax: (610) 640-4481
Email: john.urtz@siemens.com

3. Device Name and Classification

Product Name:	SOMATOM Emotion 6
Propriety Trade Name:	SOMATOM Emotion 6 (with syngo® CT VC30-easyIQ version)
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Device Name and Classification

Product Name:	SOMATOM Emotion 16
Propriety Trade Name:	SOMATOM Emotion 16 (with syngo® CT VC30-easyIQ version)
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Legally Marketed Primary Predicate Device:

Product Name:	SOMATOM Emotion 6/16
Propriety Trade Name:	SOMATOM Emotion 6/16 (with syngo® CT 2013A ((SOMARIS/5 VC20))
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Clearance Number:	K133424

Legally Marketed Secondary Predicate Device:

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:	JAK
Clearance Number:	K143401

4. Substantial Equivalence:

Siemens SOMATOM Emotion 6 and SOMATOM Emotion 16 configured with software version syngo® CT VC30-easyIQ version (SOMARIS/5 VC30) is substantially equivalent to the following medical devices in commercial distribution:

Table 1 Predicate Devices

Manufacturer	Primary Predicate Device	510(k) Number	Clearance Date
Siemens	syngo® CT 2013A (SOMARIS/5 VC20B) system software for SOMATOM Emotion 6 CT and SOMATOM Emotion 16 sysyems	K133424	01/17/2014
Manufacturer	**Secondary Predicate Device**	**510(k) Number**	**Clearance Date**
Siemens	SOMATOM Definition Edge with SOMARIS/7 VA48	K143401	04/06/2015

5. Device Description:

The SOMATOM Emotion 6 and the SOMATOM Emotion 16 are whole body X-ray Computed Tomography Systems. The SOMATOM Emotion 6 and the SOMATOM Emotion 16 produce 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, SOMARIS/5 VC30 supports the following modifications: 1) Localized language support of scan protocols, 2) Easy UI improvement, 3) Study Split Improvement, 4) FAST kV, 5) syngo. via client, 6) online help based on knowledge gateway, 7) new software field update concept 8) Temporal-MIP, 9) TrueD-4D viewer, 10) FAST 3D Align, 11) Tube Protection.

6. Indications for Use

The SOMATOM Emotion 6/16 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 resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

SOMATOM Emotion 6/16 configured with software version syngo® VC30-easyIQ version 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 remain unchanged from 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 Feature***	
New Software version syngo® CT VC30-easyIQ version	System scanner software syngo® CT 2013A **K133424**	System scanner software syngo® CT VA48 **K143401**
Temporally MIP (t-MIP)	N/A	Temporally MIP (t-MIP)
FAST 3D Align	N/A	FAST 3D Align
TrueD-4D Viewer	N/A	TrueD-4D Viewer
Fast kV	N/A	N/A
Localized Language Support of Scan Protocols	N/A	N/A
Easy UI Improvement	Easy UI	Easy UI
Study Split Improvement	Study Split	Study Split
syngo.via client	N/A	syngo.via client
Online Help Based on Knowledge Gateway	Online help available	Online help available
New Software Field Update Concept	N/A	N/A
Tube Protection	N/A	N/A

8. Nonclinical Testing:

SOMATOM Emotion 6/16 configured with software version syngo® VC30-easyIQ version 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. 3.1
- 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 – 3.14: 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, 2005
- IEC 60601-1-3: 2008, Medical electrical equipment – Part 11-3: General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6: 2010; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability

- 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
- NEMA XR-26: Access Controls for Computed Tomography—Identification, Interlocks, and Logs
- IEC/ISO 10918: Information Technology – Digital Compression and Coding of Continuous-Tone Still Images: Requirements and Guidelines [Including: Technical Corrigendum (2005)]

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 Emotion 6/16 configured with software version syngo® VC30-easyIQ version 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 Emotion 6/16 configured with software version syngo® CT VC30-easyIQ version. 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, 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 SOMATOM Emotion 6/16 configured with software version syngo® CT VC30-easyIQ version 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 syngo® CT 2013A (SOMARIS/5 VC20B) system software for SOMATOM Emotion 6 CT systems and SOMATOM Emotion 16 (K133424) 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.