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

April 16, 2015

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
51 Valley Stream Parkway, D-02
MALVERN PA 19355

Re: K143416
Trade/Device Name: Somatom Definition Flash
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 18, 2015
Received: February 26, 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,

Robert A Ochs

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

Indications for Use

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

510(k) Number *(if known)*
K143416

Device Name
SOMATOM Definition Flash

Indications for Use *(Describe)*
The Siemens SOMATOM Definition Flash system is 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)*

SIEMENS

510(k) Summary: SOMATOM Definition Flash

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

Date Prepared: November 24, 2014

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 Flash
Trade Name:	SOMATOM Definition Flash
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 Devices

Trade Name:	SOMATOM Definition Flash with Stellar Detector (SOMARIS/7 VA44)
510(k) #:	K121072
Clearance Date:	May 8, 2012
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology

SIEMENS

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 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*® 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 Flash CT system. *syngo*® VA48 (SOMARIS/7 VA48) is a further development to the SOMARIS/7 operating software cleared as part of the predicate devices.

syngo® VA48 is scanner platform software that supports the following device features:

1). New system scanner software version 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
- -Temporal MIP (t-MIP)
- -TrueD 4D Viewer

2). ADMIRE Iterative Reconstruction (option)
3). iMAR Improved Metal Artifact Reduction (option)
4). MARIS (Metal Artifact Reduction in Image Space) Option
5). HandCARE Quantitative Dose Reduction Option
6). CARE Dose4D Dose Reduction Option

There are no modifications to the hardware of the SOMATMOM Definition Flash.

SIEMENS

6. Indication for Use:

The Siemens SOMATOM Definition Flash system is 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 Devices:

The SOMATOM Definition Flash configured with software version *syngo*® SOMARIS/7 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.

Subject and Predicate Device Compared Technological Characteristics

Subject Device: SOMATOM Definition Flash with SOMARIS/7 VA48	**Primary Predicate Device: SOMATOM Definition Flash with Stellar Detector (VA44)**	**Secondary Predicate Device: SOMATOM Definition AS Open (VA46)**
New system scanner software version *syngo*® VA48 (SOMARIS/7 VA48) with supported software options	System scanner software version *syngo*® VA44 (SOMARIS/7 VA44) with supported software options	System scanner software *syngo*® VA44 (SOMARIS/7 VA44) with supported software options
New Iterative Reconstruction ADMIRE (option)	Iterative Reconstruction SAFIRE (option)	Iterative Reconstruction SAFIRE (option)
iMAR Iterative Metal Artifact Reduction (option) or MARIS Metal Artifact Reduction (option)	N/A	MARIS Metal Artifact Reduction (option)
HandCARE with Quantitative Dose Reduction Option	N/A	HandCARE with Quantitative Dose Reduction Option
CARE Dose4D Quantitative Dose Reduction Option	N/A	CARE Dose4D Quantitative Dose Reduction Option

SIEMENS

8. Performance Testing

SOMATOM Definition Flash configured with software version *syngo*® VA48 complies with 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 of 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 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.

SIEMENS

Summary

Performance tests were conducted to test the functionality of the SOMATOM Definition AS Open configured with software version *syngo*® 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 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 predicate devices were 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 Flash configured with software version *syngo*® VA48 has the same intended use and indication for use as the predicate devices.

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