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.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

October 9, 2015

Re: K152036
Trade/Device Name: SOMATOM Definition Edge, SOMATOM Definition AS/AS+
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 11, 2015
Received: September 14, 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 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)*
K152036

Device Name
SOMATOM Definition Edge, SOMATOM Definition AS/AS+

Indications for Use *(Describe)*
The Siemens SOMATOM Definition Edge, SOMATOM Definition AS/ AS+ (Project P46) systems are intended to produce cross-sectional images of the body by computer reconstruction of xray 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
FOR
SOMATOM Definition AS/AS+ and SOMATOM Definition Edge

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: August 25, 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. Importer/Distributor Establishment:
Registration No: 2240869
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Manufacturing Facility:
Siemens AG
Medical Solutions
Siemensstrasse. 1
D-91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:
Kimberly Mangum
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
40 Liberty Boulevard
Malvern, PA 19355
Phone: (610) 448-6477
Fax: (610) 640-4481
Email: kimberly.mangum@siemens.com

3. Device 1 Name and Classification

Product Name:	SOMATOM Project P46
Propriety Trade Name:	SOMATOM Definition AS/AS+
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

SIEMENS

Device 2 Name and Classification

Product Name:	SOMATOM Project P46F
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 (for Device 1):

Product Name:	SOMATOM Project P46
Propriety Trade Name:	SOMATOM Definition AS/AS+
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1750
Device Class:	Class II
Product Code:	90JAK
510(k) Number:	K143400

Legally Marketed Primary Predicate Device (for Device 2)

Product Name:	SOMATOM P46F
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
510(k) Number:	K143401

5. Indications for Use

SOMATOM Definition AS/AS+

The Siemens SOMATOM Definition AS/AS+ (Project P46) 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.)

SOMATOM Definition Edge

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:**
The subject devices Siemens SOMATOM Definition AS/AS+ and Siemens SOMATOM Definition Edge, configured with software version syngo CT VA48 are substantially equivalent to following medical devices in commercial distribution as listed in **Table 1**:

Table 1: Predicate Devices

Manufacturer	Predicate Device	510(k)	Clearance Date
Siemens	SOMATOM Definition AS/AS+ configured with software version SOMARIS/7 VA48	K143400	April 08, 2015
Siemens	SOMATOM Definition Edge configured with software version SOMARIS/7 VA48	K143401	April 6, 2015

7. **Device Description:**
The Siemens SOMATOM Definition AS/AS$^+$ and SOMATOM Definition Edge equipped with *syngo CT* VA48 are Computed Tomography X- ray Systems, which feature a continuously rotating tube-detector system and functions according to the fan beam principle. The SOMATOM Definition AS/ AS$^+$ and SOMATOM Definition Edge 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 version of system software, *syngo CT* VA48, supports functionality such as Twin Beam scanning, Fast 3D Align, TrueD 4D Viewer, Fast DE evaluation and improved functionality with extended Field of View. The computer system delivered with the CT scanner is able to run optional post processing applications.

In addition to the previously supported software functionality, which was cleared for the FAST DE Result evaluation of Dual Source and Single Source (dual spiral) data, the subject device will support the FAST DE Result evaluation of data acquired with TwinBeam technology. FAST DE Results evaluation allows to use the optional post-processing features Monoenergetic Plus and Virtual Enhanced.

8. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**
The subject device has been modified to support the use of TwinBeam datasets with FAST DE Results. For Twin Beam data, the evaluation with the available post-processing features can be preselected the same way as for Dual Source or Single Source data as realized/cleared with the predicate

devices. **Table 2** below provides a comparison of the primary features of the subject device in comparison to the predicate devices.

Table 2: Predicate and Subject Device Comparable Technological Characteristics

Property	Subject Device	Primary Predicate Device K143400	Predicate Device K143401
Software Features/ Functionality	**FAST DE Results for TwinBeam Data–** additionally support the use of TwinBeam datasets with post-processing applications Monoenegetic Plus and Virtual Unenhanced	Support of FAST DE results for dual source and single source data sets	Support of FAST DE results for dual source and single source data sets
		Support of TwinBeam scan mode	Support of TwinBeam scan mode

The subject devices SOMATOM Definition AS/AS+ and SOMATOM Definition Edge do not have significant changes in technological characteristics when compared to the primary predicate devices SOMATOM Definition AS/AS+ and SOMATOM Definition Edge configured with software version syngo CT VA48. The Indication for Use and fundamental scientific technology remains unchanged, and the operating principle is same; therefore, Siemens believes that the subject devices are is substantially equivalent to the predicate devices.

9. Nonclinical Testing:

SOMATOM Definition AS/AS+ and SOMATOM Definition Edge are designed to fulfill the requirements of the following safety and performance standards listed below:

- IEC 60601-2-44: Medical electrical equipment Part 2: Particular requirements for the safety of X-ray equipment for CT
- 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 – 3.20: 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
- 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 (integration and functional) were conducted for SOMATOM Definition AS/AS+ and SOMATOM Definition Edge configured with software version syngo CT 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 support 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.

Non-Clinical Testing Summary
Performance tests were conducted to test the functionality of the FAST DE Results for TwinBeam Data. Phantom bench testing and retrospective analysis of available patient data was conducted for application classes Monoenergetic Plus and Virtual Unenhanced for the FAST DE Results for TwinBeam Data software module. Supportive articles that demonstrate the usability of Monoenergetic Plus and Virtual Unenhanced for the FAST DE Results for TwinBeam Data software module were provided to support device performance and functionality.

In addition, 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.

SIEMENS

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

SOMATOM Definition AS/AS+ and SOMATOM Definition Edge with FAST DE Results for TwinBeam Data software module has the same intended use and comparable indication for use as the predicate devices. The technological characteristics such as image visualization, operating platform, and image manipulation are same as with the predicate devices. Any differences in technological characteristics between the subject device and the predicate devices do not raise different questions of safety or effectiveness. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

The predicate devices were cleared based on non-clinical supportive information including phantom bench test, retrospective review of available patient data, and supportive clinical articles. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The same testing and workflows were used to test the subject device modifications. 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. Since both devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM Definition AS/AS+ and SOMATOM Definition Edge with FAST DE Results for TwinBeam Data software module testing supports a finding of substantial equivalence.