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

March 28, 2016

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Technical Specialist, Regulatory Submissions
40 Liberty Boulevard, Mail Code 65-1A
MALVERN PA 19355

Re: K151749
Trade/Device Name: SOMATOM Scope/Scope Power
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 7, 2016
Received: March 9, 2016

Dear Ms. Mangum:

This letter corrects our substantially equivalent letter of March 18, 2016.

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" (21CFR 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)*
K151749

Device Name
SOMATOM Scope/Scope Power

Indications for Use *(Describe)*
The SOMATOM Scope and SOMATOM Scope Power 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740

SIEMENS

510(K) SUMMARY
FOR
SOMATOM SCOPE SYSTEMS

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Date Prepared: October 30, 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
Mail code: 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 Business Unit CR
Siemensstrasse 1
DE—91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:

Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
40 Liberty Boulevard, 65-1A
Malvern, PA 19355-1406
Phone: (610) 448-6477
Fax: (610) 640-4481
Email: kimberly.mangum@siemens.com

SIEMENS

3. Device Name and Classification

Product Name:	SOMATOM Scope
Propriety Trade Name:	SOMATOM Scope (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 Scope Power
Propriety Trade Name:	SOMATOM Scope Power (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 Scope/Scope Power
Propriety Trade Name:	SOMATOM Scope/Scope Power
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
510(k) #:	K140912

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
510(k)#:	K143401

4. Substantial Equivalence:

Siemens SOMATOM Scope/Scope Power with software version SOMARIS/5 VC30 syngo® CT VC30-easyIQ version is substantially equivalent to the following medical devices in commercial distribution.

SIEMENS

Table 1 *Predicate Devices*

Predicate Device Name and Manufacturer	510(k) number	Clearance Date
Primary Predicate Device: Siemens SOMATOM Scope/Scope Power with SOMARIS/5 VC28	K140912	09/15/2014
Secondary Predicate Device: Siemens SOMATOM Definition Edge with SOMARIS/7 VA48	K143401	04/06/2015

5. Device Description:

The Siemens SOMATOM Scope/Scope Power are Computed Tomography X- ray Systems which feature a continuously rotating tube-detector system and function according to the fan beam principle. 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 1) Localized language support of scan protocols, 2) Easy UI Improvement, 3) iMAR, 4) Study Split Improvement, 5) FAST kV, 6) e-Sleep Improvement, 7) syngo. via client, 8) Touch Panel (FAST Positioning), 9) online help based on knowledge gateway, 10) FAST Wizard, 11) new software field update concept, 12) Temporal-MIP, 13) TrueD-4D viewer, 14) RTP Enhancement 15) Adaptive Signal Boost Improvement, 16) FAST 3D Align, 17) Dual Spiral Dual Energy, 18) FAST DE Results (for Mono-energetic), 19) Tube Protection, 20) SAFIRE, 21) Modified Patient Table 22) Interleaved Volume Reconstruction (IVR)

6. Indications for Use

The SOMATOM Scope 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 xray tube, and the simultaneous translation of the patient.)

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

SOMATOM Scope/Scope Power configured with software version SOMARIS/5 VC30 syngo® CT VC30-easyIQ version do 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	Subject Device SOMATOM Scope/Scope Power	Predicate Device Comparable Feature	
		Primary Predicate Device SOMATOM Scope/Scope Power	SOMATOM Definition Edge (K143401)
Localized language support of scan protocols	Localized language support of scan protocols	N/A	N/A
Easy UI Improvement	Easy UI Improvement	Easy UI	Easy UI
iMAR	iMAR	N/A	iMAR
Study Split Improvement	Study Split Improvement	Study Split	Study Split Improvement
FAST kV	FAST kV	N/A	N/A
e-Sleep Improvement	e-Sleep Improvement	e-Sleep	N/A
syngo.via client	syngo.via client	N/A	syngo.via client
FAST Positioning	FAST Positioning	N/A	N/A
Online help based on knowledge gateway	Online help based on knowledge gateway	Online help available	Online help available
FAST Wizard	FAST Wizard	N/A	N/A
New software field update concept	New software field update concept	N/A	N/A
Temporal MIP (t-MIP)	Temporal MIP (t-MIP)	N/A	Temporal MIP (t-MIP)
True-D-4D Viewer	True-D-4D Viewer	N/A	True-D-4D Viewer
RTP Enhancement	RTP enhancement	RTP supported	RTP supported
Adaptive Signal Boost Improvement (SDF Improvement)	Adaptive Signal Boost Improvement (SDF Improvement)	Adaptive Signal Boost	N/A
FAST 3D Align	FAST 3D Align	N/A	FAST 3D Align
Dual Spiral Dual Energy	Dual Spiral Dual Energy	N/A	Dual Spiral Dual Energy
FAST 3D Results for Mono-Energetic	FAST 3D Results for Mono-Energetic	N/A	FAST 3D Results for Mono-Energetic
SAFIRE	SAFIRE	N/A	SAFIRE
Modified Patient Table	Modified Patient Table	Normal table load	N/A
Tube Protection	Tube Protection	N/A	N/A
Interleaved Volume Reconstruction (IVR)	Interleaved Volume Reconstruction (IVR)	N/A	N/A

8. Nonclinical Testing:

SOMATOM Scope/Scope Power configured with software version syngo® CT 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 – 3.20 (2011): 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 60601-1-6 : 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)]
- 60601-1-2 (2007): Medial Electrical Equipment – Part 1-2: General requirements for basic safety and essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

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 Scope/Scope Power configured with software version SOMARIS/5 VC30 syngo® CT VC30-easyIQ version during product development. The modifications described in this Premarket Notification were supported with verification/validation and performance 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.

SIEMENS

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 Scope/Scope Power configured with software version SOMARIS/5 VC30 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 Scope/Scope Power configured with software version SOMARIS/5 VC30 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 the SOMATOM Scope/Scope Power (K140912) is 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.