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

December 16, 2016

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

Re: K162302
Trade/Device Name: SOMATOM Confidence ® RT Pro
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 10, 2016
Received: November 14, 2016

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,

For

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)*
K162302

Device Name

SOMATOM Confidence ® RT Pro

Indications for Use *(Describe)*

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data. The images delivered by the system can be used by a trained physician as an aid in diagnosis.

The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

This CT system can be used for low dose lung cancer screening in high risk populations.*
*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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.

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510(K) SUMMARY
FOR
SOMATOM CONFIDENCE

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: November 9, 2016

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.

I. Submitter
Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Establishment Registration Number
2240869

Location of Manufacturing Site
Siemens Healthcare GmbH
Siemensstr. 1
D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Contact Person:
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II. Device Name and Classification

Product Name:	SOMATOM Confidence
Propriety Trade Name:	SOMATOM Confidence® RT Pro
Classification Name:	Computed Tomography X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

III. Predicate Device
Primary Predicate Device:

Trade Name:	SOMATOM Definition AS Open
510(k) Number:	K142955

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Clearance Date:	November 24, 2015
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:	Information about design related recalls are provided in **Section 18**.

Secondary Predicate Device:

Trade Name:	SOMATOM Definition Flash
510(k) Number:	K142955
Clearance Date:	November 24, 2015
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:	Information about design related recalls are provided in **Section 18.**

Reference Devices:

Trade Name:	SOMATOM Definition AS Open
510(k) Number:	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:	Information about design related recalls are provided in **Section 18.**

Trade Name:	SOMATOM Definition Flash
510(k) Number:	K121072
Clearance Date:	May 08, 2012
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:	Information about design related recalls are provided in **Section 18.**

IV. Device Description

The Siemens SOMATOM Confidence is a Computed Tomography X- ray System which features one continuously rotating tube-detector system and functions according to the fan beam principle. The SOMATOM Confidence produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens and other vendors as an aid in diagnosis, treatment preparation and therapy planning support (including, but not limited to, Brachytherapy, Particle including Proton Therapy, External Beam Radiation Therapy, Surgery). The computer

system delivered with the CT scanner is able to run the post processing applications optionally.

The platform software for the SOMATOM Confidence, syngo CT VA62A (SOMARIS/7 VA62A), is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The SOMATOM Confidence will support the following modifications in comparison to the predicate devices:

1) New Marketing Name: SOMATOM Confidence (SOMATOM Confidence® RT Pro)
2) Modified Indication for Use Statement
3) New/Modified Hardware
    - Touch Panels
    - New Gantry and Patient Table Covers
    - Stellar RT Detector
4) Software version SOMARIS/7 VA62A
    - Data Exchange with external SW Client (Teamplay)
    - IT Hardening
    - DirectDensity™
5) Update 510(k) Information

A comparison of these modifications with respect to the predicate devices in provided the "Comparison of Technological Characteristics with the Predicate Device" section below. The SOMATOM Confidence will be offered in 20 and 64 slice configurations.

V. Indications for Use

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data. The images delivered by the system can be used by a trained physician as an aid in diagnosis.

The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

VI. Comparison of Technological Characteristics with the Predicate Device

The SOMATOM Confidence provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software and hardware components of the SOMATOM Confidence have been modified or improved in comparison to the predicate device to support enhanced device functionality compared to the predicate device. The hardware components of the subject device have been modified to include a touch panel user interface, new gantry and patient table covers, and the Stellar RT Detector.

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Software version SOMARIS/7 VA62 supports software features that are designed to enhance cybersecurity, and feature DirectDensity™ which provides CT images with an HU-like scaling that is nearly proportional to relative electron density. The intended use and fundamental scientific technology for the SOMATOM Confidence remains unchanged from the predicate devices.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Scanner Principle- Whole body X-Ray Computed Tomography Scanner System Acquisition – Continuously rotating tube detector system
- X-Ray Tube – Straton MX P
- kV Steps – Adjustable kV acquisition steps
- Operating System – Windows based operating platform
- Iterative Reconstruction – Support of various optional iterative reconstruction methods
- Workplaces – Support of workplaces that include reconstruction and image evaluation software

The following technological differences exist between the subject device and predicate devices:

- Support of touch panel user interface
- Reduced width 2 cm Stellar RT Detector
- Software version VA62A
- DirectDensity™ Reconstruction, which provides CT images with an HU-like scaling that is nearly proportional to relative electron density
- Support of additional cybersecurity features

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Siemens believes that the subject device is substantially equivalent to the predicate devices.

Testing and validation is completed. Test results show that the subject device, the SOMATOM Confidence, is comparable to the predicate devices in terms of technological characteristics, safety and effectiveness and therefore is substantially equivalent.

VII. Performance Data

Non Clinical Testing

Non-clinical test (integration and functional) including phantom tests were conducted for the SOMATOM Confidence during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. Siemens claims conformance to the following performance standards: ISO 14791, NEMA XR-29, IEC 61223-2-6, IEC 61223-3-5, IEC 62304, NEMA XR-25, and DICOM 3.1-3.20.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the SOMATOM Confidence in accordance with the following standards: IEC 60601-1, 60601-2-44, and 60601-1-2. Completed Form FDA 3654 are provided within this submission.

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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. The performance data demonstrates continued conformance with special controls for medical devices containing software. The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation support the claims of substantial equivalence.

The performance testing data for optional reconstruction feature DirectDensity™ was acquired on a Siemens Healthineers SOMATOM Confidence with a Gammex 467 Tissue Characterization Phantom with varied arrangements of the tissue substitutes. Additional performance testing data for DirectDensity™ was obtained from simulations. The results of verification and validation testing demonstrate that the subject device modifications for DirectDensity™ - image values proportional to relative electron density and perform as expected. The testing results support that the requirement specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims for DirectDensity™. Safety and performance parameters have not been affected by supporting DirectDensity™. The technical characteristics supporting DirectDensity™ do not change the indication for use, safety or efficacy.

Siemens conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014" is included within this submission.

Additional Supportive Data
The National Lung Screening Trial (NLST), sponsored by the National Cancer Institute, is used to support the additional lung cancer screening Indications for Use. The study was a randomized trial of screening with the use of low-dose CT compared to chest radiography to determine whether screening with low-dose CT could reduce mortality from lung cancer. The study start date was August, 2002 and the completion date was October, 2010. The interpretation task with CT for this study was to detect lung nodules of 4mm diameter or greater.

Summary
Features described in this premarket notification are supported with verification and validation testing, supportive literature, dosimetry and imaging performance, and analysis of phantom images to assess device and feature performance during product development. 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 claim of substantial equivalence.

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.

VIII. Conclusions

The predicate devices were cleared based on the results of non-clinical testing including verification and validation, phantom tests, and supportive literature. The subject device is also tested using the same methods as used for the predicate devices. The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrates that the SOMATOM Confidence should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM Confidence performs comparably to the predicate device that is 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 Confidence testing supports a finding of substantial equivalence.