DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 21, 2016

Siemens Medical Solutions USA, Inc.
% Ms. Veronica Padharia
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

Re: K162339
Trade/Device Name: Scenium VE10 Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 19, 2016
Received: August 22, 2016

Dear Ms. Padharia:

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)*

K162339

Device Name
Scenium VE10 Software

Indications for Use *(Describe)*

The Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET and SPECT scans.

The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations.

The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest. It facilitates comparison with existing scans derived from FDG-PET, amyloid-PET, and SPECT studies, calculation of uptake ratios between regions of interest, and subtraction between two functional scans.

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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510(K) SUMMARY

AS REQUIRED BY 21 CFR PART 807.87(H) AND 807.92(C)

Identification of the Submitter

Submitter:	Veronica Padharia Regulatory Affairs Specialist Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Name / Address of Manufacturer(s)	Siemens Medical Solutions USA, Inc. Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192
Telephone Number:	(630) 877-5761
Fax Number:	(865) 218-3019
Date of Submission:	August 19th, 2016

Identification of the product

Device Proprietary Name:	Scenium VE10
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II

Predicate Marketed Device to which Equivalence is claimed:

Device Proprietary Name:	Scenium VD20
Manufacturer:	Siemens Medical Solutions USA, Inc.
Product Code:	LLZ
Device Class:	Class II
510(k) Number:	K150192

Device Description:

Scenium VD20 display and analysis software enables visualization and appropriate rendering of multimodality data, providing a number of features which enable the user to process acquired image data.

Scenium VD20 consists of three workflows:

- Database Comparison
- Ratio Analysis
- Subtraction

These workflows are used to assist the clinician with the visual evaluation, assessment and quantification of pathologies, such as dementia (i.e., Alzheimer's), movement disorders (i.e., Parkinson's) and seizure analysis (i.e., Epilepsy).

The modifications made to the Scenium VD20 software (K150192) to create the Scenium VE10 software include:

- Enabled comparative quantification between Scenium workflows
- User interface and usability improvements to improve consistency with the syngo.via platform
- Addition of new normal databases to the Database Comparison workflow
    - SPECT – HMPAO (Chang AC) normal database
    - PET – Florbetaben normal database
- Stereotactic Surface Projection (SSP) for Amyloid uptake images can now be viewed

These changes are based on current commercially available software features and do not change the technological characteristics of the device.

Scenium VE10 analysis software is intended to be run on commercially available software platforms such as the Siemens *syngo*.MI Workflow software platform (K150843).

Performance Testing / Safety and Effectiveness:

Risk Management has been ensured via risk analyses in compliance with ISO 14971:2012 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. adheres to recognized and established industry standards for development including ISO 13485 and IEC 62304.

Verification and Validation activities have been successfully performed on the software package, including assurance that functions work as designed, performance requirements and specifications have been met, and that all hazard mitigations have been fully implemented. All testing has met the predetermined acceptance values.

Traceability of the requirements specified in the requirement specifications and functional specifications are ensured during component integration, software validation and system testing.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

The device is designed and manufactured in accordance with Quality System Regulations as outlined in 21 CFR 820.

Intended Use:

A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

Indications for Use:

The Scenium display and analysis software has been developed to aid the clinician in the assessment and quantification of pathologies taken from PET and SPECT scans.

The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations.

The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest. It facilitates comparison with existing scans derived from FDG-PET, amyloid-PET, and SPECT studies, calculation of uptake ratios between regions of interest and subtraction between two functional scans.

Statement Regarding Substantial Equivalence:

There are no differences in the Indications for Use or Fundamental Technological Characteristics of the Scenium VE10 software as compared to the currently commercially available Scenium VD20 software (K150192). Both devices are used to assist the clinician with the visual evaluation, assessment and quantification of pathologies derived from brain scans.

Additionally, there have been no changes that raise any new issues of safety and effectiveness as compared to the predicate device. Based on this information as well as the documentation in support of the modifications, it is Siemens' opinion that the Scenium VE10 software, with the modifications outlined in this application, is substantially equivalent to the predicate device.