



Food and Drug Administration
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Alaine Medio
PET and PCS Regulatory Projects Manager
810 Innovation Drive
KNOXVILLE TN 37932

March 29, 2015

Re: K150192
Trade/Device Name: Scenium
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: II
Product Code: LLZ, KPS
Dated: March 5, 2015
Received: March 9, 2015

Dear Ms. Medio:

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,

A handwritten signature in blue ink that reads "Robert Ochs, Ph.D." The signature is written over a large, semi-transparent watermark of the FDA logo.

for

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

Indications for Use

510(k) Number (if known)

K150192

Device Name

Scenium VD20 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter:	<u>Primary Contact:</u> M. Elaine Medio, RAC PET and PCS Regulatory Projects Manager Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932	<u>Alternate Contact:</u> Veronica Padharia Regulatory Affairs Specialist Siemens Medical Solutions USA, Inc. Molecular Imaging 2501 Barrington Road Hoffman Estates, IL 60192
Telephone Number:	(865) 218-2703	(630) 877-5761
Fax Number:	(865) 218-3019	(847) 304-6023
Name / Address of Manufacturer	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA	
Date of Submission:	January 27, 2015	

Identification of the product

Device Proprietary Name:	Scenium VD20
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ & KPS
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

<u>Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
Scenium VD10	Siemens Medical Solutions USA, Inc	K133654 (February 28, 2014)

Device Description:

Scenium VD10 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 VD10 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 with different imaging agents, such as using Amyloid imaging agents for dementia and Alzheimer's Disease, DaTSCAN(I-123) for Parkinson's Disease and FDG-PET for epileptic seizures.

The modifications made to the Scenium VD10 software (K133654) to create the Scenium VD20 software include:

- Customized databases can now be imported and exported in the Database Comparison workflow.
- Three new FDG databases normalized to the region of the cerebellum, in addition to whole brain, were added to the Database Comparison workflow.
- Deformable Registration for Amyloid PET has been integrated in the Ratio Analysis workflow with a different algorithm.
- Launch performance decreased the time taken to display patient data in the Ratio Analysis workflow.

This change is based on current commercially available software features and does not change the technological characteristics of the device.

Scenium VD20 Analysis software is intended to be run on commercially available software platforms such as the Siemens *syngo*.MI Workflow software platform (K133644) or commercially available Siemens scanners (e.g. *symbia* Intevo (K142006), Biograph mCT (K123737)).

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.

Technological Characteristics

The Scenium VD20 software modifications are based on the commercially available Scenium VD10 software (K133654). The features introduced into Scenium VD20 had no impact on the technological characteristics already present in the commercially available predicate system.

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 is 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.

Statement Regarding Substantial Equivalence:

There are no differences in the Indications for Use or Fundamental Technological Characteristics of the Scenium VD20 software as compared to the currently commercially available Scenium VD10 software (K133654). 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 VD20 software with the modifications outlined in this application is substantially equivalent to the predicate device.
