

K121074

JUN - 8 2012

Scenium 2.0
510(k) Premarket Notification

510(k) Summary

as required by 21 CFR Part 807.87(h)

Submitter: Elaine Chang
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
810 Innovation Dr
Knoxville, TN 37932
USA

Telephone Number: (865) 218-2873

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Name / Address of
Manufacturer: Siemens Medical Solutions USA, Inc
Molecular Imaging
2501 N. Barrington Road
Hoffman Estates, IL 60192
USA

Date of Submission: April 6, 2012

Identification of the product

Device Proprietary Name: Scenium 2.0

Common Name: Picture Archiving and Communication System

Classification Name: Picture Archiving and Communication System per 21
CFR 892.2050
Emission Computed Tomography System per 21 CFR
892.1200

Product Code: LLZ and 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 1.1	Siemens Medical Solutions, LTD	K061545
Neuro Trans3D	Segami Corporation	K043441
Brass	Hermes Medical Solution	K021656

Device Description:

Scenium 2.0 display and analysis software enables visualization and appropriate rendering of multimodality data, providing a number of features which enable the user to process the acquired image data.

Scenium 2.0 is post processing and does not control the scanning features of the system.

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 and calculation of uptake ratios between regions of interest.

Technological characteristics:

The software is similar in uses and applications to the predicate devices. Both the device and predicates are used to assist the Clinician with the visual evaluation, assessment and quantification of pathologies derived from brain scans.

Safety and Effectiveness:

The device is designed and manufactured under Quality System Regulations as outlined in 21 CFR 820. All requirements of Emission Computed Tomography system standards (21 CFR 892.1200) and Picture Archiving and Communications System (21 CFR 892.2050) are met, and software is in compliance with ISO 14971 and ISO 62304.

Substantial Equivalence:

Based on the above considerations, Siemens Medical Solutions USA, Inc believes that the Scenium 2.0 software is substantially equivalent to the predicate devices. The device and the predicate devices are all post-processing and provide similar features of visualization and numerical data.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Elaine Chang
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
KNOXVILLE TN 37932

JUN - 8 2012

Re: K121074
Trade/Device Name: Scenium 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and KPS
Dated: April 6, 2012
Received: April 9, 2012

Dear Ms. Chang:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

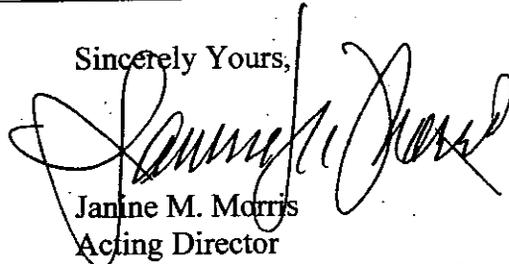
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

K121074

Device Name: Scenium 2.0

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Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Research

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