SIEMENS

ORIGINAL

510(k) SUMMARY
as required by 21 CFR Part 807.87(h)

K061545

JUN 30 2006

Company Contact Details

Submitter's Name and Address	Siemens Molecular Imaging Ltd Level 1, 23-38 Hythe Bridge Street Oxford OX1 2EP United Kingdom
Establishment registration number:	3003493157
Contact Name in UK:	Mark Evans
Contact Title:	Managing Director
Contact E-mail Address:	mark.evans@mirada-solutions.com
Telephone Number:	44-1865-265-500
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Date of Submission:	31.05.2006

Contact Details in the US:

Contact Name:	Frank Pokrop
Contact Title:	Senior Manager Regulatory Affairs
Contact Address:	Siemens Molecular Imaging Group 2501 N. Barrington Road Hoffman Estates, IL 60195

Contact E-mail Address: frank.pokrop@siemens.com

Telephone Number: (847) 304-7516

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Identification of the product

Device Proprietary Name:	Scenium 1.1
Common Name:	Emission computed tomography system, Product Code 90KPS Picture archiving and communications system, Product Code LLZ
Classification Name:	Class II: Sec 21 CFR 892.1200 and CFR 892.2050

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
Scenium	Siemens Molecular Imaging Ltd (formerly Mirada Solutions Ltd)	K042863
Syntermed NeuroQ™	Syntermed Inc	K041022
Segami NeuroGam™ on Mirage™	Segami Corporation	K043441

Device Description:

Scenium 1.1 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.

The software is post processing and does not control the scanning features of the system.

Indications for Use: K061545

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 workstations 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 facilitating comparison with existing scans derived from FDG-PET and SPECT studies.

Technological characteristics

The software is similar in uses and applications to those 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 concerns:

The device is designed and manufactured under Quality system regulations as outlined in 21 CFR § 820. All requirements of the Emission Computed tomography system Standard, as outlined in 21 CFR 892.1200 and Picture archiving and communications system CFR 892.2050 have been met, and additionally the software is in compliance with the requirements of BS EN ISO 14971:2001 – Medical Devices - Application of risk management to medical devices.

Substantial Equivalence:

Based on the above considerations, Siemens Molecular Imaging Ltd believes that the Scenium 1.1 software is substantially equivalent to the chosen 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 30 2006

Siemens Molecular Imaging Ltd.
% Mr. Frank Pokrop
Senior Manager Regulatory Affairs
Siemens Molecular Imaging Group
2501 N. Barrington Road
HOFFMAN ESTATES IL 60195

Re: K061545
Trade/Device Name: Scenium 1.1
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: KPS and LLZ
Dated: May 31, 2006
Received: June 5, 2006

Dear Mr. Pokrop:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SIEMENS

ORIGINAL

Indications for Use

510(k) Number (if known): K061545

Device Name: Scenium 1.1

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.

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Prescription Use ✓ OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061545