K072567

510(k) Summary

as required by 21 CFR Part 807.87(h)

OCT 30 2007

Identification of the Submitter

Submitter:	M. Alaine Medio, RAC
Telephone Number:	(865)218-2703
Fax Number:	(865)218-3019
Date of Submission:	September 11, 2007

Identification of the product

Device Proprietary Name:	Symbia-E
Common Name:	Gamma camera
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
e.cam	Siemens Medical Solutions USA, Inc	K963983
Siemens Enhanced Imaging System	Siemens Medical Solutions USA, Inc	K041166
Syngo MI Applications 2007A	Siemens Medical Solutions USA, Inc	K063826
c.cam	Danish Diagnostic Development	K031825
c.cam-AC	Danish Diagnostic Development	K051460

Device Description:

The Symbia-E is a gamma camera used to view and analyze images of the human body and the distribution of administered radionuclides. This system is designed for whole-body oncology, neurology, cardiology and general diagnostic examinations. The Symbia-E is intended to be utilized by appropriately trained health care professionals to image and measure the distribution of radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body.

The Symbia-E system which is the subject of this application is substantially equivalent to the commercially available e.cam gamma camera (K963983) and the commercially available Siemens Enhanced Imaging System (K041166).

The changes incorporated into Symbia E include modifications made to address obsolescence issues, cost reduction efforts and to change the industrial design of the system. Additionally, the system software has been updated (Syngo MI Applications 2007B).

Indications for Use:

To detect or image the distribution of radionuclides in the body or organ, using the following techniques: planar imaging, whole body imaging, tomographic imaging for isotopes with energies up to 588keV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 2007

Ms. M. Alaine Medio, RAC
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
Molecular Imaging Group
2501 North Barrington Road
HOFFMAN ESTATES IL 60195-5203

Re: K072567
Trade/Device Name: Symbia-E
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography system
Regulatory Class: II
Product Code: KPS
Dated: October 9, 2007
Received: October 10, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Indications for Use

510(k) Number (if known): K072567

Device Name: Symbia-E

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Prescription Use_X_ 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 K072567