K082506

510(K) SUMMARY
AS REQUIRED BY 21 CFR PART 807.87(H)

NOV 21 2008

Identification of the Submitter

Submitter:	Gunhild Paulsen
Telephone Number:	847-304-7516
Fax Number:	(847)-304-6023
Date of Submission:	August 25, 2008.

Identification of the product

Device Proprietary Name:	Symbia 4.0
Common Name:	Emission Computed Tomography System
Classification Name:	Section 21 CFR 892.1200
Product Code:	KPS
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
Siemens Enhanced Imaging System	Siemens Medical Solutions USA, Inc	K041166
Symbia E	Siemens Medical Solutions USA, Inc	K072567
syngo MI Applications 2007A	Siemens Medical Solutions USA, Inc	K063826
IP500 Nuclear Gamma Camera System	Siemens Medical Solutions USA, Inc	K952109

Device Description:

The Siemens Symbia® system is combined X-Ray Computed Tomography (CT) and Emission Computed Tomography (SPECT) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The SPECT subsystem images and measures the distribution of radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for SPECT studies and precise anatomical reference for the fused SPECT and CT images.

The system maintains independent functionality of the CT and SPECT devices, allowing for single modality CT and / or SPECT diagnostic imaging.

The **Symbia E** and **Symbia S** series are gamma cameras used to view and analyze images of the human body and the distribution of administered radionuclides.

The **Symbia T** series have an additional CT system designed to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The Symbia T series allows healthcare facilities to carry out SPECT and CT studies using the same instrument.

The **MI Workplace** is a software workstation for use with nuclear medicine applications. The **MI Applications** software functions as the primary user interface for acquiring, viewing, manipulating, post-processing and archiving images from the Siemens family of dedicated SPECT, PET and SPECT/CT and PET/CT systems.

Enhancements in Symbia 4.0 include:

1. New optional acquisition method IQ•SPECT* for cardiac imaging
   - **SMART**ZOOM* collimator
   - Cardio-centric acquisition
   - IQ•SPECT reconstruction.
2. New optional accessories; pediatric pallet, scintimamography pallet and radiation therapy pallet.
3. Single detector configuration of the commercially available Symbia E (K072567) gamma camera, Symbia E Single
4. Upgraded version of the MI Applications software (2009A)

*) Registered Trademark will be applied for

Safety and Effectiveness:

Risk Management is ensured via a risk analysis in compliance with ISO 14971 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 such as IEC 60601-1 series and 21 CFR 1020.30 and 21 CFR 1020.33 to minimize electrical, mechnanical and radiation hazards.

Siemens considers that the proposed systems do not introduce new safety concerns, and is substantially the same in design, materials, energy sources and technology as the currently marketed systems. Siemens believes that the Symbia 4.0 systems are substantially equivalent to the predicate devices.

Indications for Use:

The Siemens Symbia series is intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

SPECT: 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

CT: The CT component is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.

SPECT+CT: Perform CT scans and nuclear imaging studies with the same instrument. To obtain attenuation corrected images and to provide registration of anatomical and physiological images within the patient's anatomy.

Software: The MI Applications software is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies taken from SPECT, PET, CT and other imaging modalities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

Mr. Gunhild Paulsen
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
2501 N. Barrington Road
HOFFMAN ESTATES IL 60192

Re: K082506
Trade/Device Name: Symbia 4.0
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and JAK
Dated: August 28, 2008
Received: August 29, 2008

Dear Mr. Paulsen:

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 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting 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): K082506

Device Name: Symbia 4.0

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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 K082506

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