MAY 17 2004

K041166

510(k) Summary of Safety and Effectiveness

Submitted in accordance with 21 CFR 807.87(h)

Proprietary Device Name
Siemens Enhanced Imaging System

Establishment Name and Registration of Submitter
Siemens Medical Solutions USA, Inc.
Nuclear Medicine Group
2501 N. Barrington Road
Hoffman Estates, IL 60195
FDA Registration Number: 1423253
FDA Owner/Operator Number: 9010023

Date Prepared
March 30, 2004

Contact
Frank Pokrop
Manager, Regulatory Affairs
Phone: (847) 304-7516
Fax: (847) 304-6023
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Device Classification

Classification Code:	KPS
Panel Identification:	Radiology
Classification Name:	Emission Computed Tomography System, per 21 CFR 892.1200
Common Name:	~~Gamma Camera~~ Emission Computed Tomography System
Device Classification:	Class II

Reason for Submission
Modification of a legally marketed device

Identification of Legally Marketed Equivalent Devices

510(k) Number	Date of Clearance	Device Name
K992731	November 10, 1999	Siemens, e.Cam Computer
K952109	August 23, 1995	Siemens, Ip 500 Nuclear Gamma Camera System
K991841	August 26, 1999	General Electric, Hawkeye Option for Dual-Head Variable Angle Gamma Camera
K023687	November 22, 2002	Siemens Somatom CT System

1 of 2

Proposed Device Description

The Siemens Enhanced Imaging System is an improved version of the e.cam gamma camera that now incorporates a CT.

The gamma camera is based on hardware and software features that generate nuclear medicine images based on the uptake of radioisotope tracers in a patient's body.

The CT system is 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 Siemens Enhanced Imaging System is intended to allow healthcare facilities to carry out SPECT and CT studies using the same instrument.

Description of Change or Modification

The Siemens Enhanced Imaging System has been modified to include upgraded electrical, computer, software and mechanical performance features that produce nuclear medicine images and CT-based attenuation corrected images in order to identify regions of interest in the patient's anatomy.

The device includes updated display equipment, data storage devices, patient and equipment supports and component parts and accessories.

Intended Use

Stand alone gamma camera and a gamma camera combined with an integral CT to be used for imaging of Nuclear Medicine scans, attenuation corrected images and fusion capabilities to assist in the registration and localization of emission images within the patient's anatomy. The proposed device is capable of performing both SPECT and CT protocols on the same machine.

Comparative Analysis

The Siemens Enhanced Imaging System has been demonstrated to be as safe and effective as the predicate devices for its intended use.

Summary of Studies

The Siemens Enhanced Imaging System has successfully undergone bench and functional testing as well as software verification and validation, electrical safety and environmental testing.

Discussions and Conclusions from Nonclinical Tests:

Data regarding the functional performance of the proposed device have been generated and reviewed. The results of testing conducted to validate and verify the design modifications demonstrate acceptable performance of the device. The test results do not raise any new or additional issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Siemens Medical Solutions USA, Inc.
% Mr. Ned Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K041166
Trade/Device Name: Siemens Enhanced Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: March 30, 2004
Received: May 4, 2004

Dear Mr. Devine:

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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K041166

Device Name: Siemens Enhanced Imaging System

Indications for Use:

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 place taken at different angles or spiral planes taken at different angles.

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

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041166