K033831

DEC 1 9 2003

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. General Information

Establishment:

- Address: Siemens AG, Medical Solutions
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  D-91052 Erlangen
  Germany
- Registration Number: 3002808157
- Contact Person: Eva Reiter
  Quality Manager
  Telephone: +49 (9131) 84-2680
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Device Name and Classification:

- Trade Name: will be first marketed as SIENET Cosmos
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

- **Device Description and Intended Use:**
  This premarket notification covers Siemens' enhanced PACS system SIENET Cosmos.
  SIENET Cosmos is a "software only"- solution, including a backend communication and storage component and three different workplace deployments for medical imaging tasks and applications.

  SIENET Cosmos is the integrated radiology suite for large radiological practices and community hospitals. Important factors are the centralized server structure, the wide-ranging data distribution and the overall integrated concept, ranging from scheduling the examination to reporting and archiving as well as image and report distribution.

SIENET Cosmos Integrated Workplaces / SIENET Cosmos Image Distribution

The three SIENET Cosmos workplace deployments …

a) *syngo*® Viewing Studio - for image distribution (web-based viewing application - not intended for primary diagnosis!)

b) *syngo*® Reporting Studio - for basic reporting, inside as well as outside of the radiology (standalone workstation)

c) *syngo*® Reporting Studio - Advanced Application Bundle - for use inside the radiology with advanced reporting functionality

… are medical diagnostic and viewing workstations intended for manipulating, reading, reporting, viewing and communicating / distributing of radiological softcopy images and so allows radiologists and radiological technicians to receive and process all data needed.

SIENET Cosmos Image Data Management

… ensures all authorized personnel fast and continuous access to radiological data. It's main functionality ranges from availability of images having regard to data security, open interfaces, storage media, central system administration, back-up, software distribution to providing a flexible storage hierarchy.

The main purpose is storing and archiving of radiological softcopy images and structured (DICOM) reports.

Integration: SIENET Cosmos Imaging Workflow Management

The Workflow Management enables by integration of any HL7- / DICOM-compatible RIS (IHE Year 5) to the SIENET Cosmos PACS a consistent workflow – from patient registration to requirement scheduling to a personal worklist and supports therefore reporting, documentation or administrative tasks.

- **Technological Characteristics:**

  SIENET Cosmos is a "software only"-system, which will be delivered on CD-ROM / DVD and installed by Siemens service engineers.
  Hardware-Requirements to be met are therefore defined.

  The backend communication and storage solution (SDM) is based on the Solaris 8 operating system. The workplaces are based on Windows 2000 / Windows XP operating system.

  The herewith described SIENET Cosmos supports DICOM formatted images and objects.

- **General Safety and Effectiveness Concerns:**
  The device labelling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

- **Substantial Equivalence:**
  The SIENET Cosmos, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

SIENET Diagnostic Reporting Console (DRC)	K920309
SIENET Diagnostic Reporting Console VA02 Upgrade	K935694
SIENET Teleradiology Product Line	K955394
syngo® Multimodality Workstation	K010938
SIENET MagicWeb (Webserver), SIENET MagicLink I	K973131
SIENET Archive Server, ISA I, ISA II, Storage Server	K920310

The SIENET Cosmos described in this 510(k) has the same intended use and similar technical characteristics as the devices listed above together.

In summary, Siemens is of the opinion that SIENET Cosmos does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Siemens AG Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K033831
Trade/Device Name: SIENET Cosmos
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 28, 2003
Received: December 10, 2003

Dear Mr. Preiss:

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): K03 3831
Device Name: SIENET Cosmos

Indications For Use:

The SIENET Cosmos is a Picture Archiving and Communication System (PACS) intended to enhance the complete imaging workflow, i.e.

- Manipulating
- Reading
- Reporting
- Viewing
- Communicating / distributing
- Storing / archiving

of radiological softcopy images and

- Storing / archiving of structured (DICOM) reports.

The system is a "software only" solution and is intended to assist the physician in diagnosis or treatment planning.

Therefore SIENET Cosmos supports the following generic imaging workflow:

- Receive scheduled exams from IS at the SIENET Cosmos archiving component SDM
- Provide relevant prior exams and reports (Structured Reports only) to the Modalities and Workplaces
- Receive and store new exams from the Modalities at the SDM
- Prepare images for reading
- Report new images, if required by comparing them with prior exams and reports
- Demonstrate exams at Radiological Demos
- View exams and reports at Workplaces outside Radiology (e.g. Surgery, Intensive Care Unit, wards, external referring physicians).

Note:
The workstation deployment *syngo*® Viewing Studio is not intended for primary diagnosis.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033831

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)