510(k) Summary

JUL - 8 2004

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
  Henkestrasse 127
  D-91052 Erlangen
  Germany
- Registration Number: 2240869
- Contact Person: Ana Ladino
  Technical Specialist Regulatory Submissions
  Telephone: (610) 448-1785
  Telefax: (610) 448-1787

Device Name:

- Trade Name: LEONARDO
- Classification: Picture Archiving and Communications System (PACS)
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

Date of Preparation of Summary: April 9th, 2004

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**
  This premarket notification covers Siemens LEONARDO *syngo*-based multi-modality workplace. *syngo* is a universal imaging platform based on Windows XP. Leonardo offers a comprehensive solution to view, optimize, post-process diagnostic information and aid the doctors in the evaluation of digital radiological examinations and patient information.

Due to special customer requirements based on the modality image type and the clinical focus, the LEONARDO can be configured with different combinations of clinical applications. *syngo* applications can be added to the LEONARDO multi-modality workplace either individually or as clinical focus packages.

The LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO can be configured as a satellite console, sharing a database with the main console of a CT, MR, or radiographic/fluoroscopic imaging system, as well as stand-alone diagnostic review and post-processing workstation.

The LEONARDO can be configured with a variety of *syngo*- or Windows XP-based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

- **Technological Characteristics:**
  The LEONARDO will be marketed as a software only solution for the end-user (with recommended hardware requirements) or as a complete work station for the end-user (hardware and software package). It will be installed by Siemens service engineers. The LEONARDO supports DICOM formatted images and information. The workstation is based on the Windows XP operating system.

- **General Safety and Effectiveness Concerns:**
  The device labeling 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 LEONARDO *syngo* Multimodality Workstation, addressed in this premarket notification, is substantially equivalent to the following commercially available device:

  syngo Multimodality Workstation (K010938)

  The LEONARDO Workplace described in this premarket notification has the same intended use and similar technical characteristics as the device listed above.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2004

Ms. Ana Ladino
Technical Specialist,
Regulatory Submissions
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K040970
Trade/Device Name: LEONARDO
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 9, 2004
Received: April 14, 2004

Dear Ms. Ladino:

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): K040970
Device Name: LEONARDO

Indications for Use

The LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO can be configured as a satellite console, sharing a database with the main console of a CT, MR, or radiographic/fluoroscopic imaging system, as well as stand-alone diagnostic review and post-processing workstation.

The LEONARDO can be configured with a variety of *syngo*- or Windows XP-based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040970