K082930

NOV 14 2008

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
  Henkestrasse 127
  D-91052 Erlangen
  Germany
- Registration Number: 3002808157
- Contact Person: Sabine Schroedel
  Regulatory Affairs Manager
  Telephone: +49 (9131) 84-2680
  Telefax: +49 (9131) 84-2792

Device Name and Classification:

- Trade Name: *syngo* Imaging XS
  Version V70
- 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 *syngo* Imaging XS, version V70.

syngo Imaging XS is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images.
It supports the physician in diagnosis and treatment planning.
syngo Imaging XS also supports storage and archiving of Structured DICOM Reports.

In a comprehensive imaging suite *syngo* Imaging XS integrates Hospital/Radiology Information Systems (HIS/RIS) to enable customer specific workflows.
syngo Imaging XS optionally uses a variety of advanced postprocessing applications.

Note:
Web based image distribution is not intended for reporting.

syngo Imaging XS does not support the display of mammography images for diagnosis

syngo Imaging Workplaces

The three *syngo*Imaging XS workplace deployments ...

a) *syngo* Imaging XS Cluster Client

b) *syngo* Imaging XS Web Client

c) *syngo* Imaging XS Standalone Workstation

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

By usage of specific FDA approved monitors (Barco: Coronis dual head 21.3" Medical - K042221; Siemens AG: SMVD 21500 or DjSB-2103-D-5MP - K043122; Planar, Dome C5i-1 and C5i-2 - K032202) diagnosis on digital mammography images is possible, but is not supported by *syngo* Imaging XS, as disclaimed in the Intended Use.

Integration:

The Integration of *syngo* Imaging XS shall be applied at different levels and by using different technologies like sharing the same HW/SW platform, using common Siemens Medical components (e.g. OPENLink), offering an open interface for other vendors to connect, with other DICOM nodes and especially the DICOM Archive functionality, with other information systems (mainly RIS).

- **Technological Characteristics:**

syngo Imaging XS (version V70) is a "software only"-system, which will be delivered on CD-ROM / DVD or also preconfigured on hardware. *syngo* Imaging XS will be installed by Siemens service engineers.

Defined Hardware requirements are to be met.

The herewith described *syngo* Imaging XS 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 *syngo* Imaging XS, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Siemens	*syngo* Imaging V30	K071114
Mercury	VISAGE Pacs/CS	K072205

The *syngo* Imaging XS described in this 510(k) has the same intended use and similar technical characteristics as the device listed above in regard to the specific functionalities.

In summary, Siemens is of the opinion that *syngo* Imaging XS 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

NOV 14 2008

Siemens AG, Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K082430
Trade/Device Name: *syngo* Imaging XS (version V70)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 28, 2008
Received: October 31, 2008

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 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): K082430
Device Name: *syngo* Imaging XS (version V70)

Indications For Use:

syngo Imaging XS is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images.
It supports the physician in diagnosis and treatment planning.
syngo Imaging XS also supports storage and archiving of Structured DICOM Reports.

In a comprehensive imaging suite *syngo*Imaging XS integrates Hospital/Radiology Information Systems (HIS/RIS) to enable customer specific workflows.
syngo Imaging XS optionally uses a variety of advanced postprocessing applications.

Note:
Web based image distribution is not intended for reporting.

syngo Imaging XS does not support the display of mammography images for diagnosis.

Prescription Use X AND / OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

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

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K082430