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510(k) Summary

AUG 27 2009

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:

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Device Name and Classification:

- Trade Name: *syngo.x*
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

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## II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

### Device Description and Intended Use:

This premarket notification covers Siemens' enhanced PACS system *syngo.x*.

*syngo.x* is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo.x* based software options. *syngo.x* supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

The system is a software only medical device. It defines minimum requirements to the hardware it runs on. The hardware itself is not seen as a medical device and not in the scope of this 510(k) submission.

It supports the physician in diagnosis and treatment planning. *syngo.x* also supports storage of Structured DICOM Reports.

In a comprehensive imaging suite *syngo.x* integrates Radiology Information Systems (RIS) to enable customer specific workflows.

*syngo.x* allows to use a variety of advanced applications (clinical applications) designed for *syngo.x* just as the predicate device *syngo* MultiModality Workplace (K072728, cleared on April 22, 2007). These applications are medical devices on their own rights and filed separately. They are not part of this 510(k) submission and not part of the *syngo.x* medical device. *syngo.x* has a universal component called generic reader application which is part of this medical device and it allows no newly introduced imaging and postprocessing algorithms compared to the above mentioned predicate devices.

*syngo.x* is based on Windows. Due to special customer requirements and the clinical focus *syngo.x* can be configured in the same way as the *syngo* MultiModality Workplace with different combinations of *syngo.x*- or Windows-based software options and clinical applications which are intended to assist the physician in diagnosis and/or treatment planning. This includes commercially available post-processing software packages.

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syngo.x Data Management

... ensures all authorized personnel fast and continuous access to radiological data. It's main functionality ranges from availability of images with regard to data security, open interfaces, storage media and central system administration, to provide a flexible storage hierarchy.

Integration:

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

Technological Characteristics:

*syngo.x* is a "software only"-system, which will be delivered on CD-ROM / DVD to be installed on common IT hardware. This hardware has to fulfil the defined requirements. The Software will be installed by Siemens service engineers only.

The backend communication and storage solution is based on Windows 2008 operating system. The client machines are based on Windows XP. Any hardware platform, which complies to the specified minimum hardware and software requirements and with successful installation verification and validation activities can be supported.

The herewith described *syngo.x* supports DICOM formatted images and objects.

The *syngo.x* will be marketed as a software only solution for the end-user (with recommended hardware requirements). It will be installed by trained service engineers only. Any special needs such as integration in a specific environment and updates / upgrades will be covered by individual service contract and fulfilled by special trained service technicians.

• **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 hazards, Siemens adheres to recognized and established industry practice and standards.

• **Substantial Equivalence:**

The *syngo.x*, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

<i>Manufacturer</i>	<i>Predicate Device Name</i>	<i>FDA Clearance Number</i>
Siemens	<i>syngo Imaging</i>	K081734
Siemens	<i>syngo MultiModality Workplace</i>	K072728

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

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



Food and Drug Administration  
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Silver Spring, MD 20993-0002

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% Mr. Stefan Preiss  
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NEW BRIGHTON MN 55112-1891

**AUG 27 2009**

Re: K092519

Trade/Device Name: *syngo*®.x  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: August 12, 2009  
Received: August 18, 2009

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 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.

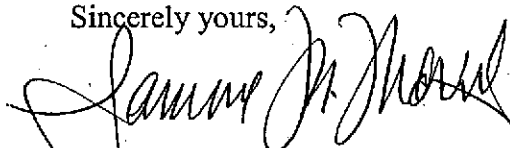
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,



Janine M. Morris  
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): K092519  
Device Name: syngo®.x

Indications For Use:

*syngo.x* is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo.x* based software options.

*syngo.x* supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

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

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

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices.

510(k) Number K092519