K081018

510(k) Summary

APR 25 2008

syngo® Dynamics (version 7.0)

Date of Summary Preparation: March 28, 2008

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

1. General Information

Specification Developer and Manufacturer Name and Address

Siemens Medical Solutions USA, Inc.
400 West Morgan Road
Ann Arbor, MI 48108

Establishment Registration Number

1836549

2. Contact Person

Sieglinde Nina West
Sr. Manager, Regulatory Affairs and Quality

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3. Device Name and Classification

Trade Name:	*syngo*® Dynamics Version 7.0
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Number:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

4. Device Description

This premarket notification covers Siemens' enhanced system *syngo*® Dynamics, version 7.0.

syngo® Dynamics is a digital image management system that includes a DICOM server. This system receives, stores, distributes, and archives images from digital image acquisition devices such as ultrasound, computer tomography, MRI and x-ray angiography machines. The system has workplaces that can be used to review, edit, and manipulate image data, as well as to generate quantitative data, qualitative data, and diagnostic reports.

syngo® Dynamics new release focuses on advanced support for cardiology users. Reporting will be enhanced with the option of interactive coronary artery diagrams or the revised cardiac wall motion scoring model. Also, *syngo* Dynamics 7.0 will add support for CR and DR image types.

Version 7.0 contains extended features for existing reporting functionality including hemodynamic data import from selected third party devices, easier serviceability and a flexible operating system support.

syngo® Dynamics is a software device that is shipped as a turn key server system with pre-installed server software on common, off-the-shelf OEM computer hardware. *syngo*® Dynamics is installed by Siemens service engineers.

The workstation with full viewing and report generation functionality is offered "software only" i.e. it will be delivered on CD or DVD media and installed by the end user or by a Siemens service engineer on the user's own computer hardware.

5. Intended Use

syngo® Dynamics is a Picture Archiving and Communication System (PACS) intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation. *syngo*® Dynamics is not intended to be used for reading of mammography images.

6. Substantial Equivalence

The *syngo*® Dynamics version, addressed in this premarket modification, is substantially equivalent to the following commercially available devices:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Product Code
syngo Dynamics 6.0 Siemens Medical Solutions USA, Inc.	K070322	02/27/2007	LLZ
syngo Dynamics 5.0 Siemens Medical Solutions USA, Inc.	K053133	12/05/2005	LLZ
Centricity GE Healthcare Integrated IT Solutions	K063628	12/26/2006	LLZ

7. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

The *syngo*® Dynamics server is a software device that is shipped as a turn key system with pre-installed software on common, off-the-shelf OEM computer hardware. The workstations with full viewing and report generation capability are delivered "software only" i.e. on CD-/DVD-media and installed by the end user on his own computer hardware. This software-only delivery mechanism does require that the customer's computer hardware meet defined requirements.

syngo® Dynamics servers use the Microsoft Windows 2003 Server operating system. The workplaces operate on the Microsoft Windows XP or the Microsoft Vista operating system.

The herewith described *syngo*® Dynamics supports DICOM-formatted images and structured report objects.

syngo® Dynamics 7.0 release adds multi-vendor hemodynamic data import, provides the option to use for reporting purpose interactive diagrams and enhanced measurements and calculations. It improves clinical reporting for many departments with its "smart" generated report text and supports customer specific workflow with the reports in formats suitable for delivery to a HIS, RIS or CIS repository.

8. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device.

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

9. Conclusion as to Substantial Equivalence

In summary, Siemens is of the opinion that *syngo*® Dynamics 7.0 does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

S. Nina West

Sieglinde Nina West
Sr. Manager, Regulatory Affairs and Quality

3/28/08

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2008

Siemens Medical Solutions
c/o Mr. Stefan Preiss
TUV SUD America Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGTON MN 55112

Re: K081018
Trade/Device Name: syngo® Dynamics (version 7.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: LLZ
Dated: March 28, 2008
Received: April 10, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

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): K081018

Device Name: ***syngo*® Dynamics (version 7.0)**

Indications for Use:

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syngo® Dynamics is not intended to be used for reading of mammography images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081018