K070322

510(k) Summary

syngo® Dynamics (version 6.0)

FEB 27 2007

Date of Summary Preparation: February 23rd, 2007

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, Inc.
400 W. Morgan Road, Suite 100
Ann Arbor, MI 48108

Establishment Registration Number

1836549

2. Contact Person

Sieglinde Nina West
Sr. Manager, Regulatory Affairs and Quality

Telephone: (734) 205-2423
Fax: (734) 998-0123
email Address: sieglinde.west@siemens.com

3. Device Name and Classification

Trade Name:	*syngo*® Dynamics Version 6.0
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 6.0.

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 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 provides advanced reporting features, including cardiology oriented features for review and analysis of x-ray angiographic images, and the capability to launch 3rd party software applications either as stand alone application or via Internet Explorer.

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

Version 6.0 contains extended features for cardiac cath viewing and reporting as well as for cardiac echo reporting. Further on *syngo*® Dynamics 6.0 includes enhanced integration of the Siemens Sequoia Ultrasound Product and the Siemens Axiom Sensis product for reporting in the cath lab environment.

syngo® Dynamics, version 6.0 also offers an optional "software only" workplace with full viewing and report generation, which will be delivered on CD-ROM and installed by the end user on his 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, 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 Siemens Medical Solutions, Inc	K053133	12/05/2005	LLZ
Xcelera Philips Medical Systems North America Company	K061995	09/06/2006	LLZ

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

syngo® Dynamics is a software device that is shipped as a turnkey system with pre-installed software on common, off-the-shelf OEM computer hardware. *syngo*® Dynamics is installed by Siemens service engineers. It is also available as a "software only" workplace with full viewing and report generation. 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 are based on the Microsoft Windows XP operating system.

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

syngo® Dynamics 6.0 release adds pediatric hemodynamics, electro-physiology, and enhanced adult cath reporting. It improves clinical reporting for many departments and supports customer specific workflow.

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 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

2/23/07

Date

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K070322 Third Party Organization: TÜV Product service

Third Party's Primary Reviewer(s): Olaf Teichert

ODE/OIVD Division: DRARD Branch/Team: Radiological Devices Branch

Section 2 – 510(k) Decision

Third party recommendation: SE √ NSE ____ Other (specify): _____

ODE/OIVD final decision: SE √ NSE ____ Other (specify): _____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	√		
b. Extent of pre-submission consultation with ODE/OIVD division			
c. Organization and format of review documentation	√		
d. Determination of 510(k) administrative completeness (screening review)	√		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	√		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	√		
g. Rationale for conclusions and recommendation	√		
h. Use of guidance documents and standards	√		
i. Resolution of 510(k) deficiencies and FDA requests for additional information			
j. Scope of reviewer expertise and use of consulting reviewers			
k. Other (specify):			

Comments (explanation of ratings/issues): _____

Section 4 – ODE/OIVD Assessor Information

Assessed by: Sunder Rajan Date: 21-Feb-2007 Tel. No.: 240 276 3968

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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

FEB 27 2007

Re: K070322
Trade/Device Name: syngo® Dynamics (version 6.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 31, 2007
Received: February 2, 2007

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 (Premarket Approval), 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). 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): _ K070322__

Device Name: ***syngo*® Dynamics (version 6.0)**

Indications for 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

/s/ Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070322