

K060992

**510(K) SUMMARY**  
**syngo US Workplace**  
**Prepared April 24, 2006**

APR 28 2006

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

**1. Submitted By:**

Siemens Medical Solutions USA, Inc., Ultrasound Division  
1230 Shorebird Way  
Mountain View, CA 94043

**Contact Person:**

Sheila W. Pickering  
Regulatory Affairs

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**Date Prepared:**

March 30, 2006

**2. Proprietary Name:**

*syngo*<sup>®</sup> US Workplace

**Common/ Usual Name:**

System, Image Processing, Radiological

**Classification Name:**

21 CFR 892.2050

Picture Archiving and Communications System 21 CFR # 892.2050

Product Code 90-LLZ

**3. Predicate Devices:**

Siemens Ultrasound Systems (K052410, K051139, K041319, K032144, K022567, K050034, K033196, K023720, K021497, K010950, K891449, K904017, K052895, K 022896) and the TomTec Image Arena (K040546)

**4. Device Description:**

The *syngo*<sup>®</sup> US Workplace is used to view images, to store and print images, and to make measurements on images using a personal computer. The software is user-installable. The images are acquired by ultrasound systems using standardized formatting and are transferred from the ultrasound system to the PC hosting the software by CD-ROM and DVD or a network connection.

**5. Intended Uses:**

*syngo*<sup>®</sup> US Workplace is used to accept and view post processed ultrasound images, to store and print images, and to manipulate and make measurements on images using a personal computer or a compatible DICOM compliant PACS system.

6. **Technological Comparison to Predicate Device:**

The *syngo* US Workplace is substantially equivalent to the Siemens family of ultrasound imaging systems and the TomTec Image Arena. The device is used to view ultrasound images, to store and print images, and to make measurements on images using a personal computer. The software is user-installable. The images are acquired by ultrasound systems using standardized formatting and are transferred from the ultrasound system to the PC hosting the software by CD-ROM, DVD or a network connection.



DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 28 2006

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Siemens Medical Solutions USA, Inc., Ultrasound Group  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K060992

Trade/Device Name: syngo<sup>®</sup> US Workstation  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: April 7, 2006  
Received: April 11, 2006

Dear Mr. Job:

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.



*Protecting and Promoting Public Health*

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.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" (21 CFR 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



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 : K060992

Device Name: syngo<sup>®</sup> US Workplace

## Indications For Use:

syngo<sup>®</sup> US Workplace is used to view post processed ultrasound images, to store and print images, and to manipulate and make measurements on images using a personal computer or a compatible DICOM compliant PACS system.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Braden  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K060992

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