SEP 1 8 2009

Section K: 510(k) Summary

K092067

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.

1. GENERAL INFORMATION

Establishment:

- Address: Siemens AG, Medical Solutions
  Henkestrasse 127
  D-91052 Erlangen
  Germany
- Registration Number: 3002808157
- Contact Person: Shelly Pearce
  Regulatory Affairs
- Telephone: (650) 694-5988

Device Name and Classification:

- Trade Name: ABVS Workplace
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

2. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**

This premarket notification covers the Siemens ABVS Workplace, an offline image viewing workstation.

The ABVS Workplace is intended to display ultrasound images of the breast acquired from B-mode imaging using an automatic or handheld scanning linear transducer. The images may be reviewed and analyzed by the physician. The ABVS Workplace is indicated for use as an adjunct to mammography. The ABVS Workplace is not intended to be used as a replacement for screening mammography.

Technological Characteristics:

The ABVS workplace consists of common IT hardware and preinstalled software to ensure that defined hardware requirements are met. The workplace is based on Windows XP.

- **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 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 ABVS Workplace is substantially equivalent to the following commercially available devices:

Manufacturer	Predicate Device Name	FDA Clearance Number	Clearance Date
U-systems	Automated Breast Ultrasound System (ABUS)	K080930	08/07/2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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

Re: K092067
Trade/Device Name: ABVS Workplace
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 3, 2009
Received: September 4, 2009

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 (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" (21CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

Section A: Indications for Use

510(k) Number (If known): K092067

Device Name: ABVS Workplace

Indications for Use:

The ABVS Workplace is intended to display ultrasound images of the breast acquired from B-mode imaging using an automatic or handheld scanning linear transducer. The images may be reviewed and analyzed by the physician. The ABVS Workplace is indicated for use as an adjunct to mammography. The ABVS Workplace is not intended to be used as a replacement for screening mammography.

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 K092067