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MammoReport[Plus]
510(k) Summary

Product Name: MammoReport[Plus]

Product Classification Name: Picture Archiving and Communications System

Product Classification Code: LLZ CFR Section: 892.2050

Classification Panel: Radiology Class II

Manufacturer: Siemens AG
Medical Solutions
Henkestrasse 127
D-91052 Erlangen
Germany

Contact Person: Debbie Peacock, Technical Specialist Regulatory Affairs
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Date Prepared: October 15, 2004

Predicate Device: MammoReport[Plus] soft copy review station (originally a part of the overall system, P030010, Siemens MAMMOMAT Novation[DR] FFDM system cleared on 8/20/04).

Device Description: The MammoReport[Plus] is essentially a software product. The software is used to accept images and CAD markers, directly intended for display (e.g. DICOM MG for presentation). The MammoReport[Plus] is a multi-modality review workstation used for presentation and manipulation of medical images including digital mammography images. It includes two high-resolution gray scale monitors (FDA approved/cleared for Mammography), or any FDA-cleared mammography monitor, 3-button mouse, keyboard and keypad. The system will use lossless compression or no compression at all when displaying mammography images.

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The minimum computer requirements are:

- Windows XP Operating system
- Intel CPU with a clock rate of 2.2 GHz or greater
- 2.0 GB RAM or greater
- 70 GB hard drive or greater, operation at 160 Mbs or greater
- CD-ROM/R/RW, DVD
- 10/100/1000 Base Network interface

Summary of Technological Characteristics of the Devices Compared to the Predicate

The proposed *syngo* MammoReport[Plus] soft copy review station combines the same ability for multimodality viewing with the Windows based operating system using a Siemens *syngo* graphical user interface (GUI) as is contained in the cleared predicate Leonardo Multimodality Workstation (K040970).

In addition, the proposed device contains the same ability to receive and display CAD markers from an approved device, as well as the ability to view multimodality and mammography images as the cleared predicate device, the Sectra IDS5 Workstation (K040376).

In addition to the cleared CRT monitors previously described in the original Siemens Mammomat Novation PMA submission, P030010, any FDA cleared TFT displays may be used as described in this PMN.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Ms. Debra Peacock
Technical Specialist, Regulatory Submissions
Siemens Medical Systems, Inc.
51 Valley Stream Parkway, E-50
MALVERN PA 19355

Re: K042868
Trade/Device Name: MammoReport^{Plus} Softcopy Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 9, 2004
Received: December 10, 2004

Dear Ms. Peacock:

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.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/dsma/dsmamain.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

1.1 Indications for Use

510(k) Number (if known): K042868

Device Name: MammoReport[Plus] Softcopy Workstation

Indications for Use

The MammoReport[Plus] is a medical diagnostic workstation for viewing, manipulation, communication, reporting and storage of medical images and data on exchange media including mammography images. It interfaces to various image storage and printing devices using DICOM or similar interface standards.

The MammoReport[Plus] used with FDA cleared monitors may be used by trained physicians for display, manipulation and interpretation of lossless compressed or non-compressed mammography images and diagnostic mammography, as well as any other DICOM multi-modality image. CAD markers created by FDA approved devices may be displayed.

Trained professionals, including, but not limited to physicians, radiologists, nurses, medical technicians and assistants, typically use the MammoReport[Plus].

(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 K042868

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)