K032096

PHILIPS

Philips Medical Systems

JUL 18 2003

510 (k) Summary

Philips ViewForum 2003

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

I General Information

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway 98021-8431 Bothell Washington USA
Contact Person	Lynn T. Harmer
Telephone Number:	425-478-7312
Prepared (date):	June 4, 2003
Device Name:	Philips ViewForum 2003
Classification Name:	System, Image Processing
Regulation number	892.2050
Classification:	Class: II
ProCode:	90 LLZ
Common/Usual Name:	Workstation
Predicate Devices:	Philips EasyVision Workstation Philips EasyVision Workstation Release 6

II Information Supporting Substantial Equivalence Determination

System Description:

The device is a software package able to run on "off the shelf" hardware components.

The basic functions of ViewForum 2003 are viewing, printing, storing, communications, transferring and quantifying images. The incorporation of the DICOM standard for medical network protocols transfers, an interface between the various system components and information exchange is facilitated, this provides compatibility with diagnostic imaging systems, printers, archival and review stations from many manufacturers.

The product will also be made available as a Plug-in version for use on other modality Workstations such as CT, PACS etc. which use suitable Hardware components.

Intended Use:

The product is an image processing workstation software package designed to run on standard PC hardware. The hardware is all "off-the-shelf" standard computer components and may be purchased independently by the end user or supplied by Philips. The ViewForum 2003 software receives image files from medical scanning devices, such as CT or MRI, or from image archives and performs viewing, image manipulation, communication and printing and quantification of images.

Safety information:

No new hazards are introduced by the development of ViewForum 2003. Hazards known during the lifecycle of the predecessor EasyVision Workstation are again considered and measurements are taken.

Substantial equivalence:

The Philips ViewForum 2003 is substantially equivalent to the EasyVision Workstation systems (K920950) and EasyVision Workstation Release 6 (K023137.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2003

Philips Medical Systems
North America Company
% Mr. Marc M. Mouser
Project Engineer/Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K032096
Trade/Device Name: ViewForum 2003
Image Processing System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 7, 2003
Received: July 8, 2003

Dear Mr. Mouser:

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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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

510(k) Number (if known): K032096
Device Name: ViewForum 2003, Image Processing System
Indications For Use:

ViewForum 2003 is an image processing workstation software package designed to run on standard PC hardware. The hardware required is made up of "off-the-shelf" standard computer components. ViewForum 2003 software receives image data from medical scanning devices such as CT and MRI, or from image archives. It performs viewing, image manipulation, communication, printing and quantification of images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032096

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21CFR 801.109)