K023137

Philips Medical Systems

PHILIPS

DEC 19 2002

510 (k) Summary

Philips "EasyVision Workstation Release 6"

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):	September 18, 2002
Device Name:	Philips EasyVision Workstation Release 6
Classification Name:	System, Image Processing
Regulation number	892.2050
Classification:	Class: II
ProCode:	90 LLZ
Common/Usual Name:	Workstation
Predicate Devices:	Philips EasyVision Workstation

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II Information Supporting Substantial Equivalence Determination

System Description:

The device is a software package able to run on "off the shelf" hardware components.
The system operating software is a standard Windows XP Professionel operating system. The application software can be divided in view, print, store and link functions. Communication with modalities such as MRI and CT and with archive systems, operates via a standardised DICOM protocol on top of a TCP/IP network.

Intended Use:

The product 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. The EasyVision Workstation Release 6 software receives image data from medical scanning devices, such as CT or MRI, or from image archives and performs viewing, image manipulation, communication, printing and quantification of images.

Safety information:

No new hazards are introduced by the development of EasyVision Workstation Release 6. Hazards known during the lifecycle of the EasyVision Workstations are again considered and measurements are taken.

Substantial equivalence:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2002

Mr. Lynn T. Harmer
Manager, Regulatory Submissions
Philips Medical Systems
North America Company
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K023137
Trade/Device Name: Philips Easy Vision Workstation Release 6
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 19, 2002
Received: September 20, 2002

Dear Mr. Harmer:

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 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:

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" (21 CFR Part 807.97). 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

K02 3137

510(K) Number (if known): _____Unknown_____

Device Name: EasyVision Workstation Release 6

Indications for Use:

The EasyVision Workstation Release 6 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. The EasyVision Workstation Release 6 software receives image data from medical scanning devices, such as CT or MRI, or from image archives and 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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023137