PHILIPS

JAN 22 1998

Philips Medical Systems

K974207

510 (k) Summary of Safety and Effectiveness

Company Name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue Shelton, CT 06484
Contact Person	Peter Altman
Telephone Number:	203-926-7031
Prepared (date):	October 31, 1997
Device Name:	Philips Easy Vision Family Workstation Option EasyCorrect
Classification Name:	Image Processing System (90 LLZ)
Common/Usual Name	Workstation
Predicate Device	Easyvision Workstation

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917
Tel: (203) 926-7674
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System Description:

The EasyCorrect package is an option to the Vascular Analysis Package. EasyCorrect will support the creation of images acquired by a digital image intensifier based system that can be compared to conventional acquired images (cassette film). Thereby the same measurements can be performed on the digital acquired image as on the conventional acquired image.

The EasyCorrect package will correct images for distortion through the following process:

Calibration and clinical images are acquired according to acquisition protocols described in documentation delivered with the system. The calibration image will be acquired with a grid phantom included in the package. The software will compare the geometric characteristics of the calibration image (taken with the grid) with the actual geometrical characteristics of the grid. The difference(s) in geometrical characteristics between the two images is a measure of the distortion(s) in the digital acquired image. By applying the result of this calculation of distortion to clinical images taken under the same conditions as the calibration grid image, the clinical images can be corrected for the distortion(s) introduced by the digital technique.

Intended Use:

Easycorrect is intended for use in situations where digital images acquired from fluoroscopic imaging systems without distortion are required. The corrected images may be either hard-copy or soft-copy. Examples of (but not limited to) such situations are: making stereotactic measurements for Radiation Treatment Planning Systems or reconstructing digital spotfilm series into composite (survey) images.

Ref 21 CFR 807.92 [57 FR 18066, Apr 28, 1992, as amended at 59 FR 64295, Dec 14, 1994]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1998

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems, Inc.
North America Company
710 Bridgeport Avenue
Shelton, CT 06484-0917

Re: K974207
EasyVision Workstation with
Easy Correct Option
Dated: November 7, 1997
Received: November 10, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

Dear Mr. Altman:

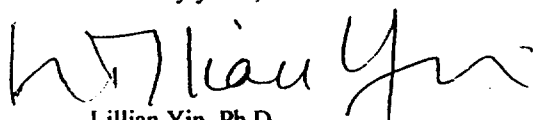
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Unknown~~ K974207

Device Name : **Philips EasyVision Workstation EasyCorrect Option**

Indications For Use :

EasyCorrect is intended for use in situations where digital images acquired from fluoroscopic imaging systems are desired or required without distortion. The corrected images may be either hard-copy or soft-copy.

(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, ENT,
and Radiological Devices
510(k) Number K974207

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

(Optional Format 1-2-96)