PHILIPS

Philips Medical Systems

K 97 3825

510 (k) Summary of Safety and Effectiveness

JAN - 6 1998

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):	July 11, 1997
Device Name:	Philips Easy Vision Family Workstation Option Vascular Analysis
Classification Name:	Image Processing System (90 LLZ)
Common/Usual Name:	Workstation
Predicate Devices:	Philips Integris, Siemens

Philips Medical Systems
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Intended Use:

The Vascular Analysis package allows for off-line image processing and manipulation of digitally acquired datasets from Integris systems. The use of the Vascular Analysis package is comparable with that on the Integris operator console (the algorithms used with the Easyvision are identical to those already used on the Intetgris systems, although the user interface is different).
With the Vascular Analysis package the user can optimize images and perceived image quality for vascular application specific purposes.

System Description.

The vascular analysis package supports the postprocessing on Digital Subtraction Angiography (DSA) images done to perform diagnosis. In a vascular study series of images are acquired either with or without contrast media. These contrast media can be iodine or CO2, and they make the vasculature visible in the image. The features in the vascular package allow for optimizing these images in the following way. Subtraction is a common used technique in DSA . Two images representing the same part of the anatomy (one with contrast media and one without contrast media) are subtracted from each other. The resulting image is an image that displays the vascular anatomy/pathology only, due to the fact that all equal anatomical structures in the two images are subtracted from each other. Thereby leaving only visible the vascular structures filled with contrast media. Run subtraction is identical to subtraction but now the subtraction process is applied to two series of images wherein image 1 of series 1 correlates w.r.t anatomy/position to image 1 in series 2.
Landmarking will allow to bring back some of the anatomical structure back into the image as to relate vascular pathology to anatomical position. Sometimes there can be a mismatch between two images that are subtracted from each other due to patient movement. To correct for this movement pixel shift is applied to the image pair, where the mask image (image without the contrast) is shifted in horizontal and/or vertical axis compared to the contrast image. This will enhance the visibility of the vascular structure only.
This can either be done:

- Manually, the user shifts in a Region Of Interest (ROI) to have an optimal result. The shift result in the ROI will be applied to the whole image.
- Split Screen, to allow different shifts in one subtracted pair. The image is either divided by a horizontal or vertical line into two areas. In each of those two areas different values of shift can be applied.
- AutoWarp, a means of enhancing a pair of subtracted images by adapting regions in the mask image to regions in the contrast image.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 1998

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

Re: K973835
Easyvision Workstation, Vascular Analysis
Package Addition
Dated: October 7, 1997
Received: October 8, 1997
Regulatory class: Unclassified
Procode: 90 LZZ

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,

William Yin

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~~ K973835

Device Name : **Philips EasyVision Workstation Vascular Analysis Option**

Indications For Use :

The **Vascular Analysis Package** is intended for off-line image processing and manipulation of digitally acquired datasets from Integris systems. The use of the Vascular Analysis package is comparable with that on the Integris operator console (the algorithms used with the Easyvision are identical to those already used on the Integris systems, although the user interface is different).

With the Vascular Analysis package the user can optimize images and perceived image quality for vascular application specific purposes.

(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 K973835

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

(Optional Format 1-2-96)