

K971965



PHILIPS

JAN 30 1998

Philips Medical Systems

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: June 23, 1997

Device Name: Philips Easyvision Family Workstation Option
Quantitative Analysis Package

Classification Name: Image Processing System
(90 LLZ)

Common/Usual Name: Workstation

Predicate Devices: Philips Gyroview HR (K921219)
GE Advantage Windows with
FuncTool Option (K960265)

Intended Use:

The **CT/MR Quantitative Analysis Package** is intended for use where visualization and analysis of CT and MR dynamic studies, showing changes in contrast over time, are useful or necessary.

System Description:

The quantitative analysis package supports the visualization and analysis of CT and MR dynamic studies which show changes in contrast over time. In a dynamic study, a time series of scans is acquired over a single or multiple slice location. The image contrast variations over time will be displayed in "Time Intensity Diagrams (TID)". These TIDs enable analysis of time dependent behavior per individual pixel, Region of Interest (ROI), or Volume of Interest (VOI). TIDs feature user definable intensity and time axes in combination with curve smoothing and curve fitting to determine modality dependent functional parameters. The functional parameters will be presented numerically and a selection of the functional parameters will be visualized as functional images. Subtraction of time series of contrast enhanced images from non-contrast enhanced images to provide the enhanced contrast only is also a function provided by the package.

Parameter analysis

Depending on the modality and the protocol used, different quantitative parameters can be computed:

=> For general CT or MR dynamic contrast studies:

maximum intensity, wash in, wash out, time to max.

=> For MR Perfusion Analysis(T2* weighted MR): regional Cerebral blood flow, time to peak, mean transit time.

Functional Images

All parameters can be computed per pixel providing new computed images. The functional images provide parameter information instead of anatomical information. These functional images can be overlaid on the anatomical images to optimize the presentation of the information to support the diagnostic process.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

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

Re: K971965
Philips EasyVision (Quantitative Analysis Option)
Dated: November 5, 1997
Received: November 6, 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/dsmmain.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~~ K971965

Device Name : Philips EasyVision Workstation Quantitative Analysis Option

Indications For Use :

The **CT/MR Quantitative Analysis Package** is indicated for use where visualization and analysis of CT and MR dynamic studies, showing changes in contrast over time are useful or necessary.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971965

Prescription Use
(Per 21 CFR 801.109

OR

Over-The-Counter Use