PHILIPS

Philips Medical Systems

K972103

510(k) Summary of Safety and Effectiveness

SEP - 2 1997

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 24, 1997
Device Name:	Philips Easyvision Family Workstation Option MR Cardiac Analysis Package
Classification Name:	Image Processing System (90 LLZ)
Common/Usual Name:	Workstation
Predicate Devices:	**Philips Gyroview HR** (K921219) **GE Advantage Windows Review Workstation** (K960613, K942120, and K913770). **Philips Gyroscan Rel 2 MR Systems** (K920578 and K920791)

Intended Use:

The **MR Cardiac Analysis Package** is intended for use in processing cardiac or cardiovascular MR images, resulting in quantitative and/or qualitative data that can be used to estimate cardiac or cardiovascular function.

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System Description:

Quantitative analysis of MR Cardio exams is normally a tedious and time consuming procedure. The **MR Cardiac Analysis Package** provides off-line viewing and processing functions for cardiac and cardio-vascular examinations, acquired with Magnetic Resonance, to simplify the process.

Historically the user had to outline the end-systolic and end-diastolic ventricle areas in one or all slices. To reduce the time required for the analysis, the **MR Cardiac Analysis Package** provides a facility for computer assisted detection of the heart boundaries of the left ventricle. The user may edit the computer generated boundary and must always approve the selection. The right ventricle boundary must still be detected manually.

To use the **MR Cardiac Analysis Package,** MR images of the heart are acquired with dedicated MR sequences at multiple slices and different phases of the heart cycle and transferred to the Easyvision Workstation. Processing these images provides data that can be used to estimate various quantitative parameters, e.g., ejection fraction, stroke volume, diastolic and systolic volume, ventricular mass, and wall thickness. It can also provide a display of cardiac functional parameters and permits correction for errors caused by papillary muscle. . All quantitative results can be printed in a dedicated, user definable, print layout for cardiac analysis, where analysis data (statistical and graphical) can be reported in combination with the image data.

The package will also provide viewing capabilities such as direct access to images, defined by slice location or heart phase, and synchronized movies for the different heart phases and/or slices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
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Re: K972103
EasyVision Family Workstation
Option: MR Cardiac Analysis
Software Package
Dated: June 2, 1997
Received: June 4, 1997
Unclassified
Procode: 90 LLZ

SEP - 2 1997

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

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~~ K972103

Device Name : **Philips EasyVision Workstation MR Cardiac Analysis Option**

Indications For Use :

The **MR Cardiac Analysis Package** is indicated for use in association with cardiac and cardiovascular examinations where it is useful or necessary to perform qualitative or quantitative analysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legenza

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972103

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

(Optional Format 1-2-96)