SEP 9 1999

PHILIPS

510 (k) Summary

K990335

Philips Medical Systems

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):	January 27, 1999
Device Name:	Philips Easy Vision Family Workstation Option Quantitative MT Analysis Package
Classification Name:	Image Processing System (90 LLZ)
Common/Usual Name	Workstation
Predicate Device	Philips Easyvision Workstation

System Description:

The **Quantitative MT Analysis** option uses MTC images created by an MR system and transferred to the EasyVision. The image contrast can be changed by calculating the ratio (based on (MT image- non-MT image)/MT image)) of the scans with and without the MT effect. The resultant image represents the percentile MT effect. The image contrast therefore becomes independent of the T1 (spin-lattice) and T2 (spin-spin) relaxation times and is defined by the MT effect alone.

Intended Use:

The Quantitative MT Analysis option on the EasyVision is intended for use in quantifying the Magnetization Transfer in tissue. The ratio image enhances the image contrast of MT sensitive tissue by the elimination of the T1 and T2 (spin-lattice and spin-spin relaxation time) effect. Visualization of Magnetization Transfer effects in sensitive tissue can improve lesion conspicuity, e.g., in white matter and cartilage.

Safety Information:

No new hazards are introduced by the addition of the Quantitative MT Analysis Option to the EasyVision Workstation.

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917
Tel: (203) 926-7674
Fax: (203) 929-6099

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1999

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, CT 06484-0917

Re: K990335
Quantitative NT Analysis Package for
Easy Vision Workstation
Dated: June 10, 1999
Received: June 11, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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~~ K990335

Device Name : **Philips EasyVision Workstation Quantitative MT Analysis Option**

Indications For Use:

The Quantitative MT Analysis option on the EasyVision is intended for use in quantifying the Magnetization Transfer in tissue. The ratio image enhances the image contrast of MT sensitive tissue by the elimination of the T1 and T2 (spin-lattice and spin-spin relaxation time) effect. Visualization of Magnetization Transfer effects in sensitive tissue can improve lesion conspicuity, e.g., in white matter and cartilage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feygin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990335

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

(Optional Format 1-2-96)