

K990329

DEC - 7

**PHILIPS****510 (k) Summary****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 21, 1999

Device Name: Philips Easy Vision Family Workstation Option
BOLD Analysis Package

Classification Name: Image Processing System (90 LLZ)

Common/Usual Name: Workstation

Predicate Device: Philips Easyvision Workstation,
GE Advantage Windows (Functool) Workstation

System Description:

The BOLD Analysis package supports the visualization and analysis of dynamic MRI studies based on Blood Oxygen Level Dependent (BOLD) contrast. The image contrast differs over dynamic scans as a result of the variation of blood oxygenation through task performance by the subject (e.g. finger tapping). BOLD data can be processed with the BOLD Analysis package to provide data analysis based on standard statistical methods.

Intended Use:

The BOLD Analysis option for the EasyVision is intended for use in analyzing images created using the BOLD function of a Gyroscan NT system. The BOLD Analysis option is useful in quantifying small susceptibility changes in the human brain, created by the execution of specific tasks.

Safety Information:

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

Philips Medical Systems
North America Company
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K990329
BOLD Analysis Package for EasyVision Workstation
Dated: September 30, 1999
Received: October 1, 1999
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Altman:

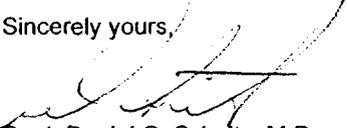
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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): K990329

Device Name : Philips EasyVision Workstation BOLD Analysis Option

Indications For Use :

The BOLD Analysis option for the EasyVision is intended for use in analyzing images created using the BOLD function of a Gyroscan NT system. The BOLD Analysis option is useful in quantifying small susceptibility changes in the human brain, created by the execution of specific tasks.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Edwin G. Stegman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K990329

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use