K973983

510 (k) Summary of Safety and Effectiveness

JAN - 8 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 **Endo 3D**
Classification Name:	Image Processing System (90 LLZ)
Common/Usual Name:	Workstation
Predicate Devices:	General Electric Medical Systems - Avantage Windows 3D with Navigator Option

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Intended Use:

The Easyvision **Endo 3D** Option is intended for use when visualization and assessment of anatomy from a perspective different from the original CT or MR data set's perspective may be either useful or necessary. This perspective can be external or internal; for example looking down on the cortex or looking inside the aorta.

System Description.

Endo 3D w is an interactive three dimensional imaging package which provides users the ability to create a visualization from a perspective different from the perspective in which the original volume data set was acquired . The process begins by transferring an MR or CT volume data set to the Easyvision workstation. The Endoview program reformats this data set according to the user's input, creating a 3D reconstruction displaying the anatomy from the perspective selected by the user. The user can then interactively select the trajectory through or around the structure.

The **Endo 3D** package combines the capabilities of two existing Easyvision functions; Trajectory MPR and 3D display. The Trajectory MPR program is intended to be used to define a path along which the simulated views will be generated. The 3D display function generates, at different locations along the defined path, a perspective three dimensional view of a region in the human body, as seen from the path. Along the path, or at any location defined in the three dimensional view, other views can be shown simulating the "fly through" or "fly around" of the anatomical object. The final result will be an interactive survey through the defined region of the patient anatomy.

Free navigation through the complex anatomy can be guided by the defined Trajectory MPR or with the aid of user defined positions. The orientation is guided by the resulting MPR along the trajectory, combined with perpendicular MPR, MIP, and/or 3D reference images. It results in an effortless journey along the selected course.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 1998

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

Re: K973983
Endo 3D Option for Easyvision Workstation
Dated: October 17, 1997
Received: October 20, 1997
Regulatory class: II
21 CFR 892.1750/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/dsmamain.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**

Device Name : **Philips EasyVision Workstation Endo 3D Option**

Indications For Use :

The Easyvision **Endo 3D Option** is intended for use when visualization and assessment of anatomy from a perspective different from the original CT or MR data set's perspective may be either useful or necessary. This perspective can be external or internal; for example looking down on the cortex or looking inside the aorta. The Endo 3D option also provides visualization of structures to facilitate surgical planning.

(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 K973983

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

(Optional Format 1-2-96)