MAY 1 2 1999

PHILIPS

510 (k) Summary

K990455

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):	February 11, 1999
Device Name:	Philips Easy Vision Family Workstation Legs Option
Classification Name:	Image Processing System (90 LLZ)
Common/Usual Name	Workstation
Predicate Device	Philips Easyvision Workstation, Spine Option

System Description:

The Legs Option uses a series of images of the skeletal leg anatomy generated with a digital fluoroscopic X-ray system and reconstructs these images as a single composite image of the complete skeletal anatomy of the lower limbs.

Intended Use:

The EasyVision Legs option enables visualization, (digital) registration, and measurement of the lower limb skeletal geometry. Diagnosis of leg length discrepancies (when both legs are acquired in the same image), as well as length and angle information on anatomical and mechanical axis are supported through the measurement tools provided.

Safety Information:

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

Philips Medical Systems
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 1999

Frank Gianelli
Senior Regulatory Affairs Specialist
Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917

Re: K990455
Philips EasyVision Family Workstation
Option: Legs Option
Dated: February 11, 1999
Received: February 12, 1999
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Gianelli:

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): K990455

Device Name: Philips EasyVision Legs Option

Indications for Use:

The EasyVision Legs option is intended for visualization, registration, and measurement of the lower-limb skeletal geometry.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990455

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

(Optional Format 1-2-96)