Philips Medical Systems Nederland B.V.
Business Group Digital Imaging Systems
PMG Common Imaging Subsystems

PHILIPS

APR 8 2005

510(k) Summary

K050692

The following information is being submitted in accordance with the requirements of 21CFR 807.92.

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway P.O.Box 3003 Bothell, WA 98041-3003, USA
Registration No.:	1217116
Contact Person: Telephone No.:	Lynn Harmer (425) 487-7312
Date Prepared:	March 14, 2005
Device (Trade) Name:	FLXIS
Classification Names:	Image intensified fluoroscopic X-ray system 21CFR892.1650, Class II (code 90JAA)

Predicate Device:
FLXIS is substantially equivalent to the OmniDiagnost Eleva, both manufactured by Philips Medical Systems Nederland B.V. The OmniDiagnost Eleva received a 510(k) substantially equivalent determination in K032046 on July 17th, 2003.

Device description:
FLXIS is a family of image detection components including image intensifiers, a camera, an image processing functionality and a remote control user interface, of which several systems can be configured. Each configuration can be delivered with a display module.

Intended use:
FLXIS is intended to visualize anatomical structures by converting a pattern of X-radiation into a visible image through electronic amplification.

General Safety and Effectiveness information:
The device and its labeling will comply with the applicable requirements of:

- Title 21 Code of Federal Regulations, Subchapter J - Radiological Health, parts 1010, 1020.30, 1020.32.
- Underwriters Laboratories standard for Safety UL60601-1 and be classified by Underwriters Laboratories (UL).
- ACR/NEMA DICOM digital imaging communication standard.

Conclusion:
FLXIS does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems Nederland B.V. considers FLXIS to be substantially equivalent with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 2005

Ms. Lynn Harmer
Manager, Regulatory Affairs
Philips Medical Systems North America
22100 Bothell Everett Highway
Post Office Box 3003 98141-3003
BOTHELL WA 98021-8431

Re: K050692
Trade/Device Name: FLXIS
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: March 15, 2005
Received: March 17, 2005

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050692
Device Name: **FLXIS**
Indications for Use:

FLXIS is intended to visualize anatomical structures by converting a pattern of X-radiation into a visible image through electronic amplification.

Prescription Use yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050692