JUL 17 2003

PHILIPS

## Philips Medical Systems Nederland B.V.

# 510(k) Summary

K030046

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

| | |
|---|---|
| Company Name:<br>Address: | Philips Medical Systems North America Company<br>22100 Bothell Everett Highway<br>P.O.Box 3003<br>Bothell, WA 98041-3003, USA |
| Registration No.: | 1217116 |
| Contact Person:<br>Telephone No.: | Lynn Harmer<br>(425) 487-7312 |
| Date Prepared: | June 12, 2003 |
| Device (Trade) Name: | Philips OmniDiagnost Eleva |
| Classification Names: | Stationary X-ray system,<br>21CFR892.1680, Class II (code 90KPR)<br><br>Image-intensified fluoroscopic X-ray system,<br>21CFR892.1650, Class II (code 90JAA)<br><br>Angiographic X-ray system,<br>21CFR892.1600, Class II (code 90IZI) |

**Predicate Device**:
The OmniDiagnost Eleva is substantially equivalent to the Philips OmniDiagnost manufactured by Philips Medical Systems. The OmniDiagnost system received a 510(k) substantially equivalent determination in K982993 on August 26, 1998.

**Device description:**
The Philips OmniDiagnost Eleva is a multifunctional, universal, overtable X-ray system offering radiographic, fluoroscopic, angiographic, and interventional techniques in a wide variety of applications. The Philips OmniDiagnost Eleva consisting of a floor mounted stand with an integrated tilting patient support table. The table is supported at only one end, allowing patient access from both sides.

As a fully integrated system, the Philips OmniDiagnost Eleva stand can be configured with X-ray generators from the Philips generator family and Philips digital spot film device. The system comes with a 38 cm multimode Image Intensifier, XTV imaging system, collimator for patient positioning without X-rays, Philips glass or metal X-ray tubes, and TV monitors.

PHILIPS

K032941 pg 2

**Intended use:**
The Philips OmniDiagnost Eleva is a diagnostic-imaging device intended for radiographic, fluoroscopic, angiographic, and interventional applications.

**General Safety and Effectiveness:**
The device and their labeling will comply with the applicable requirements of:

- 21 CFR, Subchapter J - Radiological Health, parts 1020.30, 31, 32
- Underwriters Laboratories Standard for Safety UL 2601-1 and be classified by Underwriters Laboratories.
- ACR/NEMA DICOM digital imaging communication standard.

**Conclusion:**
The Philips OmniDiagnost Eleva does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the OmniDiagnost Eleva 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

JUL 17 2003

Philips Medical Systems
North America Company
% Mr. Marc Mouser
Project Engineer/Program Manager
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607

Re: K032046
Trade/Device Name: Philips OmniDiagnost Eleva
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: 90 IZI, JAA, and KPR
Dated: June 30, 2003
Received: July 2, 2003

Dear Mr. Mouser:

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 (PMA), it may be subject to 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 the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

510(k) Number if Known): K032046

Device Name: Philips OmniDiagnost Eleva

Indications for Use:

The Philips OmniDiagnost Eleva is a diagnostic imaging device intended for radiographic, fluoroscopic, angiographic, and interventional applications.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032046