OCT 3 0 2002

PHILIPS

K023441

Philips Medical Systems

510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 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:	Lynn Harmer
Telephone No.:	(425) 487-7312
Date Prepared:	September 27, 2002
Device (Trade) Name:	Philips Multidiagnost Eleva
Classification Name:	Fluoroscopic X-ray System, 21 CFR 892.1600 class II (90 IZI)

Predicate Device:
The Philips MultiDiagnost Eleva is substantially equivalent to the Philips MultiDiagnost 4 manufactured by Philips Medical Systems. The Philips MultiDiagnost 4 system received a 510(k) substantially equivalent determination in K961374 on August 19, 1996.

Device description:
The Philips MultiDiagnost Eleva is a multi-functional, tilting C-arm system 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, it can be configured with generators from the Philips Optimus family and Digital Imaging systems. The system comes with a 38 cm multi mode Image Intensifier, XTV imaging system, collimator with laser cross for patient positioning without x-rays, Philips glass or metal x-ray tubed, and TV monitors.

22100 Bothell Everett Highway
Bothell, Washington 98021-8431
(425) 487 7000

Indications for Use:
The Philips MultiDiagnost Eleva is intended for the same applications as the previous MultiDiagnost 4 and MultiDiagnost 3 systems. As a multi-functional/universal system, general R/F, Fluoroscopy, Radiography and Angiography can be performed along with more specialised interventional applications. This includes the following general areas.

Digestive System:
Swallowing studies, Oesophagus, Stomach, Small intestine, Colon, Defeacography, ERCP, T-tube cholangiogram, Liver biopsies, Transjugular Intrahepatic Portosystemic Shunts (TIPS).

Skeletal System:
Bone studies.

Urinary System:
IVP, Cystograms, Percutaneous Nephrolithotomy, Nephrostomy tube placement.

Reproductive System:
Hysterosalpingograms, Vena spermatica, Cavernography.

Various Iodine:
Arthrograms, Myelograms, Facet joint injections, Discography, Sialography.

Respiratory System:
Bronchoscopy, Pulmonary biopsies.

Circulatory System:
Venography, Arteriography, Thrombolytic Therapy, Embolizations, Embolectomy, TVC filter placement, Dilatations, Stent placement.

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 and 1040.10
- Underwriters Laboratories Standard for Safety UL 2601-1 and be classified by Underwriters Laboratories.
- ACR/NEMA DICOM digital imaging communication standard.

Conclusion:
The Philips MultDiagnost 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 MultiDiagnost 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

OCT 30 2002

Philips Medical Systems
North America Company
% Michael Kwan, Ph.D.
Office Coordinator, 510(k) Review
Program Medical Device Services
Underwriters Laboratories, Inc.
1655 Scott Blvd.
SANTA CLARA CA 95050-4169

Re: K023441
Trade/Device Name:. Philips Multidiagnost Eleva
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: 90 IZI
Dated: October 10, 2002
Received: October 15, 2002

Dear Dr. Kwan:

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 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:

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" (21 CFR Part 807.97). 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): ~~Unknown~~ K023441

Device Name: Philips MultiDiagnost Eleva

Indications for Use:

The MultiDiagnost Eleva is indicated for use in Radiographic/Fluoroscopic, Angiographic, and Interventional diagnostic imaging examinations.

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

David A. Ayres

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023441

Prescription Use (Per 21 CFR 801.109) ✓