JUN 17 2003

K031535

510 (k) Summary

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

COMMANY NAME:	Philips Medical Systems North America Company
ADDRESS:	22100 Bothell Everett Highway P.O. Box 3003 Bothell , WA 98021-3003, USA
CONTACT PERSON:	Lynn Harmer
Telephone No.:	425-487-7312
DATE PREPARED:	May 15,2003
CLASSIFICATION NAME:	Table 21CFR 892.1980 (90IXR) Spot-film Device 21CFR 892.1670 (90IXL) Class II
COMMON/USUAL NAME:	R/F System (R/F Table)
DEVICE (Trade) NAME:	PHILIPS EasyDiagnost Eleva
REGISTRATION No.	1217116

PERFORMANCE STANDARDS:

This device complies with the federal X-Ray performance standards (CFR 1020.30, .31, .32) as well as with the relevant national and international standards for Electrical and Mechanical Safety (UL 2601, IEC 60601-1, IEC 60601-2-7).

SYSTEM DESCRIPTION:

The Philips EasyDIAGNOST is a multi-functional R/F system consisting of a floor-mounted tilting patient support table and a spotfilm device holding an image intensifier and the TV camera. The tabletop can be moved by motor in longitudinal and lateral directions. The spot film device tilts with the table, and can be moved in three directions, relative to the table and to the patient. As a fully integrated system, it can be configured with generators from the Philips Velara familiy, with digital spot film cameras from the Philips DI family, and with a Philips ViewForum workstation. The system comes with a 4-mode Image Intensifier, XTV imaging system, Philips glass or metal X-ray tube(s), and TV monitor(s). An optional dedicated ultrasound system (Ultramark 400C) can also be added.

inside the table and/or on a bucky wallstand (so-called second plane). This second plane option is identical to a Philips bucky DIAGNOST system, except for the table itself.

Philips Grid Controlled Fluoroscopy (GCF) can be provided using an SRM (metal) grid-switched X-ray tube. GCF improves overall image quality and provides dose reduction through precise control of fluoroscopic pulse shapes, eliminating excess radiation associated with pulse ramping and trailing effects of conventional pulsed fluoroscopy. The system supports system-wide application-oriented presets and can be equipped with options for better integration into the hospital IT environment (bidirectional RIS coupling), advanced X-ray control techniques (in-pulse control), dose awareness (dose calculation or measurement, automatic prefilter setting), image handling (automatic iamge transfer to integrated viewing workstation), and postprocessing (overview image reconstruction).

PREDICATE DEVICE:

The Philips EasyDiagnost Eleva is a modification of, and substantially equivalent to, the Philips EasyDIAGNOST manufactured by Philips Medical Systems. The EasyDIAGNOST received 510(k) clearance March 21, 1997 (see 510(k) K970640). The Eleva control concept was cleared by the FDA for the Philips MultiDiagnost Eleva (see 510(k) K023441). The intended use of the Philips EasyDiagnost Eleva is the same as for the Philips EasyDIAGNOST. Both systems make use of equivalent technology.

GENERAL SAFETY INFORMATION:

The Philips EasyDiagnost Eleva uses mature technology and is designed to be in compliance with National and International safety standards.

A hazard analysis on the changes to the previous device identified measures necessary to ensure that the new device is as safe and efficient as the previous device. Those measures are implemented and have been verified.

The results of the hazard analysis, combined with the appropriate preventive measures taken indicate the device is of minor level of concern, as per the August 29, 1991 issue of the "Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems North America
22100 Bothell Everett Highway
Post Office Box 3003 98041-3003
BOTHELL WA 98021-8431

Re: K031535
Trade/Device Name: Phillips EasyDiagnost Eleva
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
Regulation Number: 21 CFR 892.1670
Regulation Name: Spot-film device
Regulation Number: 21 CFR 892.1980
Regulation Name: Tilting Radiographic table
Regulatory Class: II
Product Code: JAA, KPR, IXL, and IXR
Dated: May 15, 2003
Received: May 19, 2003

Dear Ms. Harmer:

This letter corrects our substantially equivalent letter of June 17, 2003.

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 (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.

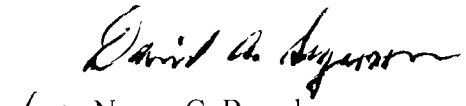
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 (240) 276-0120. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

ıdications for Use Statement

510(k) Number (if known) K031535

Device Name *Philips EasyDiagnost Eleva*

Indications for Use The *Philips EasyDiagnost Eleva* intended use is for the following applications: as a multi-functional/universal system, general R/F, Fluoroscopy, Radiography and Angiography can be performed along with pediatric examinations and some more specialized interventional applications. This includes the following examples:

Routine Examinations
Colon examinations
Examinations of the digestive tract
Lung fluoroscopy
Examinations of the gall bladder
Thorax examinations
Skeleton imaging
Pediatric examinations

Special Applications (might require special accessories and technique)
Angiography
Myelography
Phlebography
Arthrography
Bronchography
Tomography
Sialography
Hysterosalpingography

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

David R. Seyran

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031535