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PHILIPS

Philips Medical Systems

K023440

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 30, 2002
Device (Trade) Name:	Philips Digital Imaging option release 1
Classification Name:	Cine or spot fluorographic x-ray camera, 21 CFR 892.~~1920~~ 2050 Class II (~~90 IZJ~~) 90 LLE

Predicate Device:
The Philips Digital Imaging option release 1 is substantially equivalent to the Philips DSI, release 3.2, manufactured by Philips Medical Systems. The Philips DSI, release 3.2 received a 510(k) substantially equivalent determination in K920793 on July 17, 1992.

Device description:
The Digital Imaging is an option to the RF-Diagnost Eleva system family, comprising of an image processing subsystem that consists of digital imaging hardware & software. It receives digital images from the CCD camera in the RF-Diagnost Eleva system and is intended to be placed in the examination room.

The MultiDiagnost Eleva system is an X-ray systems for RF diagnostic and interventional vascular procedures. The Philips MultiDiagnost features a remote controlled C-arm stand that can be configured with a 38 cm Image Intensifier.

The Digital Imaging for the MultiDiagnost Eleva system allows the user to acquire digital images to be postprocessed, and reviewed on the examination monitor. The progressive display black and white output signal is suitable for CRT or LCD monitor types. The (RIS) patient data provided by the system controller can be merged with the images.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Philips Medical Systems
% 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: K023440
Trade/Device Name: PHILIPS Digital Imaging Option Release 1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
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 K023440

Device Name: Philips Digital Imaging option release 1

Indications for Use:

The Digital Imaging option release 1 is intended to assist physicians for diagnostic purposes and is required for interventional procedures, providing digital functionality as Last Image Hold, Digital Subtraction and contains a user interface for viewing, reviewing and processing digital images. The Digital Imaging option release 1 includes the following features, such as :

1. Providing Digital Acquisition or Fluoroscopy for Philips RF systems.
2. Diagnostic and/or Interventional applications.
3. Live subtracted acquisition and fluoroscopy for vascular applications.
4. Single or multiple images can be acquired and reviewed.
5. Sending digital images to printer, external workstations for post processing and reconstructions, PACS.

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

Prescription Use ✓

David A. Segmon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023440