K063781

510(k) Summary of Safety and Effectiveness

JAN - 5 2007

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems North America Company herewith submits a Summary of Safety and Effectiveness.

MANUFACTURER:	Philips Medical Systems DMC GmBH Roentgenstrasse 24 Hamburg, Germany D-22335
Establishment Registration No.:	3003768251
SUBMITTER:	Philips Medical Systems 22100 Bothell Everett Highway Bothell, WA 98021-8431
Establishment Registration No.:	1217116
Contact:	Lynn Harmer 425-487-7312
DATE PREPARED:	11 November 2006
CLASSIFICATION NAME:	System, image processing, radiological, Class II (LLZ) Solid State X-Ray Imager (Plat Panel/Digital Imager), Class II (MQB)
COMMON/USUAL NAME:	Digital image acquisition workstation
TRADE/PROPRIETARY NAME:	PHILIPS XD-S Direct Radiography Workstation/Package

PERFORMANCE STANDARDS:

This device complies with the federal X-Ray performance standards (CFR 1020.30, .31) as well as with relevant national and international standards for Electrical Safety (UL 60950-1, IEC 60950-1, UL 60601-1, IEC 60601-1) as well as international standards for Electromagnetic Compatibility (IEC-601-1-2, CISPR-11) and the ACR/NEMA DICOM digital imaging communication standard.

SYSTEM DESCRIPTION:

The *Philips XD-S* is a workstation (computer, keyboard, display, mouse), combined with a flat solid state X-ray detector. It is used by the operator to preset examination data, and to generate, process and handle digital X-ray images.

As a part of a radiographic system, the *Philips XD-S* is intended to acquire, process, store, display, and export digital radiographic images. The *Philips XD-S* is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding mammography.

The complete X-ray system would further include other subsystems and components, like patient table, X-ray control(s), X-ray high voltage generator, X-ray tube(s), collimator(s), accessories, etc.

There is a standalone version with minimal integration into the X-ray system. With the fully integrated version, the workstation screen also provides displays area and controls for X-ray generator control. The workstation computer can also host parts of the system control software.

Available options are:

- touch-screen monitor
- image stitching
- PCR image plate reader connection
- second flat detector
- X-ray generator user interface integration
- direct printer connection

INTENDED USE:

As part of a radiographic system, the Philips XD-S is intended to acquire, process, store, display, and export digital radiographic images. The Philips XD-S is suitable for all routine radiography exams, including specialists areas like intensive care, trauma, or pediatric work, excluding mammography

EQUIVALENCE INFORMATION:

The *PHILIPS XD-S Direct Radiography Workstation/Package* is considered substantially equivalent to the *Philips Digital Diagnost*, which received FDA marketing on November 25, 1998, under the name *Philips Bucky Vision* in 510(k) Number K982795.
In relation to the image plate reader connection, the *PHILIPS XD-S* is substantially equivalent to the *Philips Computed Radiography,* which received FDA marketing on December 18, 1996, under 510(k) Number K964124.

SAFETY INFORMATION:

The Philips XD-S Direct Radiography Workstation/Package uses mature technology. It is designed to be in compliance with National and International safety standards well as the DICOM communication standard.

Image data are not compressed for storage and the applied image processing is fully reversible.

The software used in the Wokstation is equivalent to the software used in the predicate devices. The Level of Software concern is MINOR as determined according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May/11/2005.

A product risk mangement is executed according to ISO 14971 and all risks are reduced to an acceptable level by implementation and verification of appropriate measures.

Philips Medical Systems North America Company feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Philips Medical Systems North America Company
% Mr. Marc M. Mouser
Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

JAN - 5 2007

Re: K063781
Trade/Device Name: PHILIPS XD-S Direct Radiography Workstation/Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 20, 2006
Received: December 21, 2006

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 (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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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/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

K06 3781

Indications for Use

510(k) Number (if known): K06 3781

Device Name: **PHILIPS XD-S Direct Radiography Workstation/Package**

Indications For Use:

As a part of a radiographic system, the *Philips XD-S* is intended to acquire, process, store, display, and export digital radiographic images. The *Philips XD-S* is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding mammography.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K06 3781