

5 - 510(k) Summary of Safety and Effectiveness

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
22335 Hamburg
Germany
Establishment Registration No.: 3003768251

SUBMITTER: Philips Medical Systems
22100 Bothell Everett Highway
Bothell, WA 98041-3003
Establishment Registration No.: 1217116
Contact: Lynn Harmer
425-487-7312

Date Prepared: March 06, 2009

CLASSIFICATION NAME: Solid State X-Ray Imager (Flat Panel/Digital Imager)
Class II
MQB
21 CFR 892.1650

COMMON/USUAL NAME: Solid State X-Ray Imager (Flat Panel/Digital Imager)

TRADE/PROPRIETARY NAME: Wireless Portable Detector FD-W17

PERFORMANCE STANDARDS:

This device complies with the federal X-Ray performance standards (CFR 1020.30, .31)

SYSTEM DESCRIPTION:

As a part of a radiographic system, the Wireless Portable Detector FD-W17 is intended to acquire digital radiographic images.

Wireless Portable Detector FD-W17 510(k) Submission

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The Detector is combined with a *Philips XD-S* workstation (K063781) which consists of a computer, keyboard, display, mouse.

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

The XD-S workstation and the complete X-ray systems are not changed other than by replacing an X-ray receptor with the *Wireless Portable Detector FD-W17*.

INTENDED USE:

As a part of a radiographic system, the *Wireless Portable Detector FD-W17* is intended to acquire digital radiographic images. The *Wireless Portable Detector FD-W17* is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.

EQUIVALENCE INFORMATION:

The *Wireless Portable Detector FD-W17* is considered substantially equivalent to the *Pixium 4600* detector, which received FDA clearance on November 24, 1998, under the name *Philips Bucky Vision* in 510(k) Number K982795.

The grid suppression pre-processing is equivalent to the pre-processing used by the *Konica Minolta Regius Console CS 2000/CS-3000* (K051523).

The other parts of the workstation are equal to the *Philips XD-S Direct Radiography Workstation/Package*, which received FDA clearance on January 05, 2007, under 510(k) Number K063781.

SAFETY INFORMATION:

The *Wireless Portable Detector FD-W17* uses mature technology. It is designed to be in compliance with relevant national and international standards for electrical safety (UL 60601-1, IEC 60601-1), radiation protection (IEC 60601-1-3) and Electromagnetic Compatibility (IEC-60601-1-2).

The wireless transmission of data is evaluated in risk management and tested under worst case scenarios. The Center for Devices and Radiological Health (CDRH) draft guidance "Radio-Frequency Wireless Technology in Medical Devices" from January 3, 2007 was used in preparing tests and documentation for the wireless functionality.

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

CONCLUSION:

Philips Medical Systems believes that the Wireless Portable Detector FD-W17 is substantially equivalent to the currently legally marketed devices. It does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K090625
Trade/Device Name: Wireless Portable Detector FD-W17
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 7, 2009
Received: March 9, 2009

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Dear Mr. Job:

This letter corrects our substantially equivalent letter of March 24, 2009.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

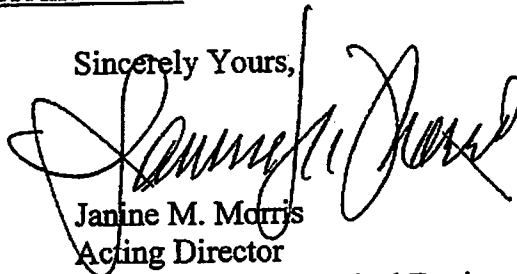
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090625

Device Name: **Wireless Portable Detector FD-W17**

Indications For Use:

As a part of a radiographic system, the *Wireless Portable Detector FD-W17* is intended to acquire digital radiographic images. The *Wireless Portable Detector FD-W17* is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.

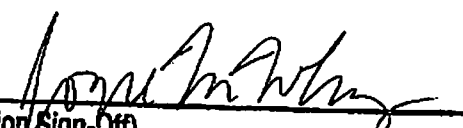
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090625