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PHILIPS

Philips Medical Systems

K042867

510(k) Summary

Philips Orthopaedic Applications

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I General Information

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway Bothell Washington 98021-8431 USA
Contact Person	Lynn T. Harmer
Telephone Number:	425-478-7312
Prepared (date):	September 24, 2004
Device Name:	Philips Orthopaedic Applications
Classification Name:	Image Processing System
Regulation number	892.2050
Classification:	Class: II
ProCode:	90 LLZ
Common/Usual Name:	Workstation
Predicate Devices:	Agfa Corporation: IMPAX® OT3000 Orthopedic Workstation Sectra Imtec AB: Sectra Orthopedic Package

K042817

II Information Supporting Substantial Equivalence Determination

System Description:

The Philips Orthopaedic Applications software runs on "off the shelf" standard PC components using a Microsoft Operating System. It can be used as stand-alone SW applications or as a Plug-in on advanced image processing workstations or review workstations (PACS).

These applications provide digital alternatives for the tools medical specialists are used to work with when using conventional images printed on film: callipers, pencil, transparent sheets, scissors and tape. The software tools transform these conventional tools for working with digital images on a computer display.

Intended Use:

Philips Orthopaedic Applications is a suite of software applications designed to assist medical professionals such as Orthopaedic surgeons, physicians and radiologists in planning and evaluating Orthopaedic procedures using medical images.

The applications are intended to view and manipulate 2D and 3D medical images; to calibrate and make length, angle and area measurements on such images; to represent and manipulate surgical planning templates overlaid on such images; to plan and simulate the effect of treatments by transforming such images; and to print and store the results of these measurements and simulations.

The software packages are designed to run on standard PC hardware ("off the shelf" standard computer components) and are available as stand-alone applications or as plug-ins for specified advanced image processing workstations or review workstations (PACS).

General Safety and Effectiveness:

The Orthopaedic Applications complies with ACR/NEMA DICOM digital imaging communication standard.

Conclusion:

The Philips Orthopaedic Applications does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Orthopaedic Applications to be substantially equivalent to the Agfa IMPAX® OT3000 Orthopedic Workstation (K040334) and the Sectra Orthopedic Package (K031590).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Philips Medical Systems
North America Company
% Ms. Melissa J. DeGuia
Associate Project Engineer/
Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K042867
Trade/Device Name: Philips Orthopaedic Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 15, 2004
Received: October 18, 2004

Dear Ms. DeGuia:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (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

Indications for Use

510(K) Number (if known): ~~Unknown~~ K042867

Device Name: Philips Orthopaedic Applications

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042867