K060749

Philips Medical Systems Nederland B.V.
Veenpluis 4-6, 5684-PC, Best
The Netherlands

APR 4 2006

PHILIPS

510(k) summary

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

Identification of submitter

Company:	Philips Medical Systems North America Company
Registration number:	1217116
Contact person:	Lynn Harmer
Telephone:	(425) 487-7312
Date prepared:	February 14, 2006

Identification of manufacturer

Company:	Philips Medical Systems Nederland B.V.
Address:	Veenpluis 4-6, 5684-PC, Best, The Netherlands
Registration number:	3003768277

Device identification

Trade name:	XperCT
Optional to:	"Xper" family of angiography X-ray systems: • Allura Xper FD10 • Allura Xper FD20 • Allura Xper FD10/10 • Allura Xper FD20/10
Classification names:	Angiography X-ray system & Stationary X-ray system

Legally marketed device

Trade name:	DynaCT
Manufacturer:	Siemens
510(k) number:	K042646

Device description

Device description:	XperCT is a software option on the Allura Xper product family. It reconstructs 3D volumes from rotational fluoroscopy acquisitions, and provides CT-like images.

Intended use

Intended use:	XperCT is a software option on the Allura Xper product family. It reconstructs 3D volumes from rotational fluoroscopy acquisitions, and provides CT-like images that assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up.

Technological characteristics

Conclusion:	XperCT is substantially equivalent to the currently legally marketed device DynaCT of Siemens, which has been cleared for marketing under K042646. This opinion is based on the following: • XperCT does not introduce new indications for use, • XperCT has the same technological characteristics as the predicate device, • XperCT does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

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

Re: K060749
Trade/Device Name: XperCT Software Option
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: March 16, 2006
Received: March 20, 2006

Dear Mr. Job:

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/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

Indications for Use

510(k) Number (if Known): K060749

Device Name: XperCT software option

Indications for Use:

XperCT is a software option on the Allura Xper product family intended for imaging bone, soft tissue and other body structures. It reconstructs 3D volumes from rotational fluoroscopy acquisitions, and provides CT-like images to assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up.

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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K060749