K130893
Page 1 of 2

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Date Prepared: March 29, 2013

General Information

Manufacturer:
Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC, Best, The Netherlands
Establishment Registration Number:
3003768277

SEP 0 6 2013

Contact Person:
Ms. Liselotte Kornmann, PhD
Regulatory Affairs Manager
Philips Medical Systems Nederland B.V.
Veenpluis 4-6,
5684 PC, Best, The Netherlands
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E-mail: Liselotte.Kornmann@philips.com.

Device Name and Classification:

Device Trade Name:	XperCT
Device name:	XperCT Rel. 3
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Regulation:	21CFR §892.1650
Classification Panel:	Radiology
Device Class:	Class II
Product code:	OWB, JAK

Legally Marketed Predicate Devices:

Trade Name:	XperCT
510(k) Clearance:	K060749
Clearance Date:	April 4, 2006
Classification Name:	Angiographic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21CFR §892.1600
Device Class:	Class II
Product Code:	IZI

Device description:

The XperCT Rel. 3 is a software medical device intended to provide high-speed and high resolution 3D cross-sectional imaging in the angiography lab.

The XperCT Rel. 3 generates a 3D image that visualizes soft tissue, which helps in identifying anatomy, for example cerebral, abdominal, and peripheral, etc., from a single rotational scan.

The XperCT Rel. 3 includes filters to improve the image quality of the reconstruction by reducing the noise caused by metal objects or other objects that absorb high levels of x-ray radiation.

Indications for Use:

The XperCT Rel. 3 reconstructs 3D volumes from rotational fluoroscopic acquisitions, and provides CT-like images that assist the physician with diagnosis, surgical planning, interventional procedures, and treatment follow-up.
XperCT Rel. 3 helps to manually estimate the dimension of the lesion.

Technology:

The XperCT Rel. 3 is a software medical device, which is provided on the hosting software functionality platform of the currently marketed Interventional Workspot Rel. 1 (K121296 - Jan 2, 2013).

The XperCT Rel. 3 software medical device employs the same fundamental scientific technology as the currently marketed and predicate software medical devices, Philips XperCT Rel. 1.

Non-clinical Performance Data:

Non-clinical verification and validation tests were performed with regards to the requirement specifications and risk management results, specifically including software verification, validation conformance testing. The test results demonstrate that the XperCT Rel. 3 software medical device complies with international recognized standards as detailed in this premarket submission and met the acceptance criteria.

Conclusion:

The XperCT Rel. 3 software medical device is substantially equivalent to the currently marketed and predicate software medical devices, Philips XperCT Rel.1 based on the design functionality, indications for use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 6, 2013

Philips Medical Systems Nederland B.V.
% Ms. Liselotte Kornmann
Regulatory Affairs Manager
Veenpluis 4-6
5684 PC, Best
THE NETHERLANDS

Re: K130893
Trade/Device Name: XperCT Rel. 3
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAK
Dated: July 22, 2013
Received: July 24, 2013

Dear Ms. Kornmann:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130893

Device Name: XperCT Rel. 3

Indications for Use:

Indications For Use: The XperCT Rel. 3 reconstructs 3D volumes from rotational fluoroscopic acquisitions, and provides CT-like images that assist the physician with diagnosis, surgical planning, interventional procedures, and treatment follow-up. XperCT Rel. 3 helps to manually estimate the dimension of the lesion.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130893