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

K102005

PHILIPS

510(k) summary

AUG - 9 2010

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

Identification of manufacturer

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

Identification of U.S. designated agent

Company:..... Philips Medical Systems
Address:..... 22100 Bothell Everett Highway
Bothell, WA 98021-8431, U.S.A.
Registration number:..... 1217116

Identification of official correspondent

Name:..... Lynn Harmer
Position:..... Senior Manager, Regulatory Affairs
Telephone:..... (425) 487-7312
Date prepared:..... June 25, 2010

Device identification

Trade name:..... Philips
Device name:..... Allura Xper FD OR Table series
Regulation description:..... Angiographic X-ray System
Regulation number:..... 21CFR 892.1600
Class:..... II
Product code:..... 90IZI

Legally marketed devices

Trade names:..... Philips Integris Allura series, Philips Allura Xper FD10,
Philips Allura Xper FD20,
Siemens Axiom Artis, Siemens Artis Zee family,
Siemens Artis Zee / Zeego family
Manufacturer:..... Philips and Siemens
510(k) numbers:..... K002016, K041949, K033737, K021021, K073290,
K090745

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Intended Use:
The Allura Xper FD OR Table series is intended for use on human patients (within the limits of the used OR table) to perform:
• Vascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
• Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
• Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

Combined with a qualified, compatible OR table, the Allura Xper FD OR Table series can be used for imaging in the Hybrid OR within the applications domains Neuro, Vascular, Non Vascular and Cardiac. The OR table can also be used standalone for surgical use in the OR.

Device description:
The Allura Xper FD OR Table series is a modular X-ray systems series, based on a set of components that can be combined into different single and biplane configurations to provide specialized angiography. It is identical to the Allura Xper FD systems series, to which a qualified, compatible OR table component is added.

These Allura Xper FD OR Table series X-ray systems are Angiographic X-ray Systems consisting of 1 or more of the following components: X-ray generator, X-ray tube/housing assembly, beam limiting device, image receptor, X-ray control, frontal/lateral stand, patient support and a monitor ceiling suspension.

Substantial equivalence:
The Allura Xper FD OR Table series was compared to its predicate devices. Evaluations were carried out based on the comparison of the intended uses and device descriptions from 510(k) summaries of the predicate devices versus the new Allura Xper FD OR Table series.

Philips Healthcare believes that the Allura Xper FD OR Table series is as safe and effective, and performs in a substantially equivalent manner to the predicate devices.

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Summary of Non-Clinical and Clinical performance tests:
Non-clinical verification and validation tests were performed to verify and validate the system functionally for the intended use relative to the specifications and risk management requirements. Results of the conducted tests conclude that the Allura Xper OR Table series is substantial equivalent to its predicate device. The following standards were used in the development of the product: or we could say the system conforms tot the following standards:

Standard:	Title
IEC 60601-1, 2nd Ed. + Amendment No. 1 + Amendment No. 2 + Corrigendum	General requirements for safety
IEC 60601-1-1, 2nd Ed.	Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2, ed 2.1	Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-3, 1st Ed.	Collateral standard: General requirements for radiation protection in diagnostic X-Ray equipment
IEC 60601-1-4 Ed 1.1	Collateral standard: Safety requirements for programmable electronic systems
IEC 60601-2-7 2nd Ed.	Particular requirements for the safety of high voltage generators
IEC 60601-2-28, 1st Ed.	Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-32 1st Ed.	Particular requirements for the safety of associated equipment of X-ray equipment
IEC 60601-2-43, 1st Ed	Particular requirements for the safety of X-Ray equipment for Interventional procedures
IEC 62304, 1st Ed.+ Corrigendum NEN-EN-IEC 62304:2006/C11:2008	Medical device software – Software life cycle processes
IEC 62366, 1st Ed	Medical devices. Application of usability engineering to medical devices
ISO 14971: 2007-10-01	Medical devices – Application of risk management to medical devices

No clinical performance test was required to show safety and effectiveness of the Allura Xper FD OR Table series in the intended clinical environment.

Conclusion:
The testing reported in this 510(k) establishes that the Allura Xper FD OR Table series is safe and effective for its intended use and is substantially equivalent to the currently legally marketed devices.

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

Philips Medical Systems North America
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

JUL 19 2013

Re: K102005
Trade/Device Name: Allura Xper OR Table Series
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: July 14, 2010
Received: July 15, 2010

Dear Mr. Job:

This letter corrects our substantially equivalent letter of August 5, 2010.

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,

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

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Indications for Use

510(k) Number

Device Name

AUG - 9 2010

Allura Xper OR Table Series

Indications for Use

The Allura Xper OR Table Series is intended for use on human patients (within the limits of the used OR table) to perform:

- Vascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
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Combined with a qualified, compatible OR table, the Allura Xper OR Table Series can be used for imaging in the Hybrid OR within the applications domains Neuro, Vascular, Non Vascular and Cardiac. The OR table can also be used standalone for surgical use in the OR.

Device description:
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General Safety and Effectiveness:
To facilitate safe and efficacious operation of the system by a trained healthcare professional, instructions for use are provided as part of the device labelling, as well as a basic training at system handover.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102005