MAR 0 5 2014

PHILIPS

K133292
Page 1 of 3

510(k) Summary

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

Date Prepared:	January 27, 2014	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684-PC, Best, The Netherlands Establishment Registration Number: 3003768277	
Contact:	Mr. Klien van Dam, PhD Regulatory Affairs Manager +3140 2795225	
Device Trade Names:	Allura Xper FD series Allura Xper OR Table series	
Classification	Classification Name:	Image-intensified fluoroscopic X-ray system
	Classification Regulation:	21 CFR 892.1650
	Classification Panel:	Radiology
	Device Class:	II
	Primary product code:	OWB
	Secondary product code	JAA
Predicate Device #1	Device Name	AlluraClarity Xper FD series X-ray system
	Manufacturer	Philips Medical Systems Nederland B.V.
	510(k) number	K130638
	Classification Regulation	21 CFR 892.1650
	Device Class:	II
	Product Code:	OWB
Predicate Device #2	Device Name	Allura Xper FD OR Tables Series
	Manufacturer	Philips Medical Systems Nederland B.V.
	510(k) number	K102005
	Classification Regulation	21 CFR 892.1650
	Device Class:	II
	Product Code:	Primary code: OWB Subsequent code: JAA

Device Description: The Allura Xper family consists of the Allura Xper FD series and the Allura Xper OR Table series and is identified as Allura Xper FD R8.2. The Allura Xper FD R8.2 is a modular angiographic X-ray system, based on a set of components that can be combined into different single and biplane configurations to provide specialized angiography. Combined with a qualified, compatible OR table, the Allura Xper FD R8.2 can also be used for imaging in the Hybrid OR. The Allura Xper FD R8.2 is optionally provided with ClarityIQ technology, which utilizes the advanced XRES4 noise reduction algorithms to reduce quantum noise in X-ray images.

Indications for Use:

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

- Vascular, cardiovascular 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.

Additionally:

- The Allura Xper and Allura Xper OR Table series is compatible with a hybrid Operating Room.
- Allura Xper FD10 is compatible with specified magnetic navigation systems.
- 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.

Technology:

The Allura Xper FD R8.2 has the same technological characteristics compared to the predicate devices. Modifications implemented in the Allura Xper FD R8.2 include the introduction of a new, state of the art FD20 X-ray detector with passive cooling, and a higher DQE. Additionally, a new high voltage X-ray generator with reduced size is introduced.

Based on the information provided in this premarket notification, the Allura Xper FD R8.2 is considered substantially equivalent to the currently marketed and predicate devices in terms of:

- Design and functionality
- Indications for use
- Fundamental Scientific Technology
- Performance specifications and testing

Non-clinical Performance Data:

The Allura Xper R8.2 complies with the following international and FDA recognized consensus standard and FDA Guidance Documents:

- IEC 60601-2-43,
- IEC 60601-2-28,
- ISO 14971;
- IEC 62304,
- FDA Guidance document entitled, "Guidance for the

Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

- FDA Guidance document entitled, "General Principals of software Validation; Final Guidance for Industry and FDA Staff" issued January 11, 2002.
- FDA Guidance document entitled, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" issued August 6, 1999.

The test results demonstrate that the Allura Xper FD R8.2:

- Complies with the aforementioned international and FDA-recognized consensus standards and/or FDA guidance documents
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the Allura Xper FD R8.2 is substantially equivalent to the currently marketed and predicate devices in terms of safety and effectiveness.

Clinical Performance Data: The subject of this premarket submission, the Allura Xper FD R8.2, did not require clinical studies to support substantial equivalence. Sample clinical images that demonstrate diagnostic quality of the images are provided.

Conclusion: The Allura Xper FD R8.2 is substantially equivalent to the predicate devices in terms of design features, fundamental scientific technology, indications for use and safety and effectiveness. The changes implemented in the Allura Xper FD R8.2 System do not render the system to be Not Substantial Equivalent.

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

March 5, 2014

Philips Medical Systems Nederland B.V.
% Klien van Dam, Ph.D.
Veenpluis 4-6
5684 PC Best
THE NETHERLANDS

Re: K133292
Trade/Device Name: Allura Xper FD series; Allura Xper OR Table series
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: II
Product Code: OWB, JAA
Dated: January 27, 2014
Received: February 7, 2014

Dear Dr. van Dam:

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" (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/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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133292

Device Name
Allura Xper series and Allura Xper OR Table series

Indications for Use *(Describe)*
The Allura Xper series and the Allura Xper OR Table series (within the limits of the used OR table) are intended for use on human patients to perform:

- Vascular, cardiovascular 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.

Additionally:

- The Allura Xper and Allura Xper OR Table series is compatible with a hybrid Operating Room.
- Allura Xper FD10 is compatible with specified magnetic navigation systems.
- 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*