K130842

MAY 2 1 2013

510(k) Summary of Safety and Effectiveness

Device Name: The proposed **Allura Xper FD X-ray imaging systems with the SSD spacer removed** include the following:

- Allura Xper FD OR Table series;
- Allura Xper FD10 series;
- Allura Xper FD20 series;
- Allura Xper FD Biplane series.

Classification: Classification Name: 21 CFR, Part 892.1600 – Angiographic x-ray system
Classification: Class II
Classification Panel: Radiology
Product Code: IZI

Date Prepared: January 18, 2013

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

Contact: Dr. Jos van Vroonhoven
Standardization manager

Predicate Devices: The predicate devices of the proposed **Allura Xper FD X-ray imaging systems with the SSD spacer removed** include the following Allura Xper FD X-ray imaging systems with the SSD spacer mounted (also manufactured and marketed by Philips Medical Systems Nederland B.V.):

- Allura Xper FD OR Table series (**K102005 - cleared by FDA on August 9, 2010**);
- Allura Xper FD10 series (**K041949 - cleared by FDA on July 30, 2004**);
- Allura Xper FD20 series (**K033737 - cleared by FDA on December 9, 2003**);
- Integris Series Release 2 (**K984545 – cleared by FDA on February 25, 1999**). Note: the Integris Series Release 2 systems are currently marketed as Allura Xper FD Biplane series.

Device Description: The proposed **Allura Xper FD X-ray imaging systems with the SSD spacer removed** are identical to the currently marketed and predicate Allura Xper FD X-ray imaging systems with the source-skin distance spacer (SSD spacer) mounted onto the X-ray tube housing, except that the SSD spacer is removed. Removal of the SSD spacer allows the execution of electrophysiology (EP) surgical procedures that require mounting of a special frame of currently marketed mapping systems (such as BioSense Webster's CARTO frame or Location Pad, etc.) underneath the patient table. With the BioSense Webster's CARTO frame mounted underneath the patient table, the SSD spacer mounted onto the X-ray tube housing of the currently marketed and predicate Allura Xper

FD X-ray imaging systems interferes with the C-arc rotations during EP procedures, thus necessitating the removal of the SSD spacer. By construction, the source-skin distance cannot become smaller than 30 cm when the SSD spacer is removed. This minimum SSD complies with the international product safety standards IEC 60601-2-43 and IEC 60601-2-54 and with the minimum distance of 20 cm as required per 21 CFR, Part 1020.32(g) for certain specific surgical procedures.

Intended Use: The proposed **Allura Xper FD X-ray imaging systems with the SSD spacer removed** and the currently marketed and predicate Allura Xper FD X-ray imaging systems with the SSD spacer mounted are indicated 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.

Combined with a qualified, compatible Operating Room (OR) table, the Allura Xper FD OR Table X-ray imaging systems 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 stand-alone for surgical use in the OR.

Non-clinical Test Data: The performance of the proposed **Allura Xper FD X-ray systems with the SSD spacer removed** is equivalent to the performance of the currently marketed and predicate Allura Xper FD X-ray imaging systems, since the removal of the SSD spacer has no effect on the performance of the X-ray tube, the collimator, the flat solid-state X-ray detector, the hardware and the software.

Substantial Equivalence to Predicate Devices: The proposed **Allura Xper FD X-ray imaging systems with the SSD spacer removed** are substantially equivalent to the currently marketed and predicate Allura Xper FD X-ray imaging systems with the SSD spacer mounted, in terms of design, indications for use, principle of operations, performance, hardware and software.

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 Nederland B.V.
% Dr. Jos Van Vroonhoven
Veenpluis 4-6
5684 PC Best
NETHERLANDS

May 21, 2013

Re: K130842
Trade/Device Name: Allura Xper FD series with the SSD spacer removed
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: IZI
Dated: January 29, 2013
Received: April 22, 2013

Dear Dr. Vroonhoven:

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,

Michael D. O'Hara 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): K130842

Device Name: Allura Xper FD series with the SSD spacer removed

Indications for Use:

The Allura Xper FD X-ray imaging systems are indicated 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.
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Prescription Use ___YES___	AND/OR	Over-The-Counter Use ____NO___
(Part 21 CFR 801 Subpart D)		(21 CFR 807 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)

Michael D. O'Hara

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

510(k) K130842