DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 29, 2016

Philips Medical Systems Nederland BV
% Ms. Jeanette Becker
Regulatory Affairs Manager
Veenpluis 4-6
Best, 5684PC
NETHERLANDS

Re: K161563
Trade/Device Name: Allura Xper FD Series and 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
Dated: June 3, 2016
Received: June 6, 2016

Dear Ms. Becker:

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 Industry and Consumer Education 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 Industry and Consumer Education 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

Robert Ochs, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161563

Device Name

Allura Xper FD 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

Date Prepared:	June 03, 2016	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Ms. Jeanette Becker Regulatory Affairs Manager Phone: +31 611386380 E-mail: jeanette.becker@philips.com	
Secondary Contact Person:	Ms. Liselotte Kornmann, PhD Senior Manager Regulatory Affairs Phone: +31 611621238 E-mail: liselotte.kornmann@philips.com	
Device:	Trade Name:	**Allura Xper FD series and Allura Xper OR Table series**
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	OWB (Interventional x-ray system)
Predicate Device:	Trade Name:	*Allura Xper FD series and Allura Xper OR Table series*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K141979 (August 19, 2014)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB

Device description: The basis for this 510(k) Premarket Notification is to expand the marketing claims of the currently marketed *Allura Xper FD series and the Allura Xper OR Table series* (K141979, August 19, 2014) provided with the ClarityIQ technology with the following marketing claim for the neuroendovascular indications:

In routine neuroendovascular procedures, the AlluraClarity system with ClarityIQ technology may reduce patient dose (as dose-area product) by as much as 62% (in routine diagnostic neuroendovascular procedures) and as much as 65% (in routine interventional neuroendovascular procedures)** for the total procedure without affecting the procedural performance (fluoroscopy time and number of DSA images) as compared to equivalent procedures on an Allura Xper system, as demonstrated in one single-center study.****

** Routine neuro interventions comprise of DSA and fluoroscopy usage.*

*** (95% CI 56%, 68% for routine diagnostic neuroendovascular procedures, 95% CI 58%, 71% for routine interventional neuroendovascular procedures). The results of the application of dose reduction techniques will vary depending on the clinical task, patient size, anatomical location and clinical practice. The interventional radiologist assisted by a physicist as necessary has to determine the appropriate settings for each specific clinical task.*

**** Results based on total dose area product from a single center retrospective historically controlled cohort study (Karolinska Hospital - Solna, Sweden) on 614 patients (302 for Allura Xper and 312 for AlluraClarity) undergoing neuroendovascular procedures.*

[Söderman M, Mauti M, Boon S, Omar A, Marteinsdóttir M, Andersson T, Holmin S, Hoornaert B. Radiation dose in neuroangiography using image noise reduction technology: a population study based on 614 patients. Neuroradiology. 2013; 55:1365-1372]

In this 510(k) Premarket Notification no changes have been made to the indications for use, technological characteristics, and performance of the **Allura Xper FD series and the Allura Xper OR Table series** provided with the ClarityIQ technology when compared to the currently marketed device.

The **Allura Xper FD series and the Allura Xper OR Table series** is a modular angiographic X-ray system, which is based on a set of components that can be combined into different single and biplane configurations to provide specialized angiography. The **Allura Xper FD series and the Allura Xper OR Table series** provided with optional ClarityIQ technology (cleared in K130638) utilizes the advanced XRES4 noise reduction algorithms to reduce quantum noise in X-ray images. Combined with a qualified, compatible OR table, the Allura Xper FD series can also be used for imaging in the Hybrid Operating Room.

Indications for Use: The indications for use of the **Allura Xper FD series and Allura Xper OR Table series** provided with ClarityIQ technology is **identical** to the currently marketed *Allura Xper FD series and the Allura Xper OR Table series*:

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.*

Therefore, the **Allura Xper FD series and Allura Xper OR Table series** provided with the marketing claims for the ClarityIQ technology is substantially equivalent to the currently marketed device in terms of indications for use.

Technological characteristics: In this 510(k) Premarket Notification no changes have been made to the technological characteristics of the currently marketed *Allura Xper FD series and the Allura Xper OR Table series*.

Therefore, the **Allura Xper FD series and Allura Xper OR Table series** provided with the new marketing claims for the ClarityIQ technology is substantially equivalent to the currently marketed device in terms of technological characteristics.

Performance Data: The following performance data was provided in support of the substantial equivalence determination for the new marketing claims for the neuro-endovascular indications for use.

<u>Clinical data</u>
A single center retrospective clinical study with 620 patients was conducted outside the United States. Of the 620 patients, 614 were eligible for analysis, 302 for Allura Xper system (without ClarityIQ technology) and 312 for AlluraClarity system (with ClarityIQ technology).
The purpose of this study was to quantify the procedural patient radiation dose reduction with the AlluraClarity system for neuroendovascular procedure and to assess its impact on the performances of the physician, in comparison to the Allura Xper system. Procedures were classified as either diagnostic or interventional.
The primary endpoints were radiation dose measurements per procedure: Dose Area Product (DAP) fluoro, DAP exposure and DAP total (sum of DAP fluoro

and DAP exposure); Cumulative Air Kerma (CAK) values for frontal and lateral channel. To evaluate the effect of the physician awareness of the system in use, secondary endpoints such as procedure time, fluoroscopy time, number of acquired exposure images and number of acquired exposure runs, were collected. In conclusion, in routine diagnostic and interventional neuroendovascular procedures, the AlluraClarity system reduced patient radiation dose by 62% (95%CI of 56%, 68%) and 65% (95%CI of 58%, 71%) respectively over the total procedure without affecting the procedural performances (fluoroscopy time and number of DSA images) compared to equivalent procedures on an Allura Xper system.

The clinical performance data as documented in the clinical study supports the new marketing claims for the neuroendovascular indications for use.

Therefore, the **Allura Xper FD series and Allura Xper OR Table series** provided with the new marketing claims is substantially equivalent to the currently marketed device in terms of safety and effectiveness.

Substantial Equivalence Conclusion:

The **Allura Xper FD series and Allura Xper OR Table series** with the new marketing claims of the ClarityIQ technology for the neuroendovascular indications is substantially equivalent to the currently marketed *Allura Xper FD series and the Allura Xper OR Table series* (K141979) in terms of indications for use, technological characteristics and safety and effectiveness.

The additional claims do not impact the device from a safety or performance perspective. Therefore, substantial equivalence can be claimed in this 510(k) Premarket Notification. The clinical study demonstrates that the **Allura Xper FD series and Allura Xper OR Table series** provided with the new marketing claims of the ClarityIQ technology in the neuroendovascular indications does not raise any new safety and/or effectiveness concerns.