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

January 26, 2017

Philips Medical Systems Nederland B.V.
% Ms. Jeanette Becker
Senior Regulatory Affairs Manager
Veenpluis 4-6
5684 PC Best
THE NETHERLANDS

Re: K163715
Trade/Device Name: Allura Xper R9
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: December 23, 2016
Received: December 30, 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)*

K163715

Device Name
Allura Xper R9

Indications for Use *(Describe)*

The Allura Xper R9 series (within the limits of the used Operating Room table) are intended for use to perform:
• Image guidance in diagnostic, interventional and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular and neuro procedures.
• Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.

Additionally:
• The Allura Xper R9 series can be used in a hybrid Operating Room.
• The Allura Xper R9 series contain a number of features to support a flexible and patient centric procedural workflow.

Patient Population:
All human patients of all ages. Patient weight is limited to the specification of the patient table.

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:	December 22, 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 Senior 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 R9**
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	Primary Code: OWB Subsequent Code: JAA
Predicate Device:	Trade Name:	*Allura Xper R9*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K162148 (November 23, 2016)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	Primary Code: OWB Subsequent Code: JAA
Reference Device:	Trade Name:	*2D Quantitative Analysis*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K161839 (July 29, 2016)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650

Classification Panel:	Radiology
Device Class:	Class II
Product Code:	Primary Code: OWB Subsequent Code: LLZ

Device description: The **Allura Xper R9** is classified as an interventional fluoroscopic X-ray system. The primary performance characteristics of the **Allura Xper R9** interventional fluoroscopic X-ray system include:

- Real-time image visualization of patient anatomy during procedures
- Imaging techniques and tools to assist interventional procedures
- Post processing functions after interventional procedures
- Storage of reference/control images for patient records
- Compatibility to images of other modalities via DICOM
- Built in radiation safety controls

This array of functions offers the physician the imaging information needed to perform minimally invasive interventional procedures.

The **Allura Xper R9** is available in a comparable set of configurations for monoplane models as the currently marketed and predicate devices *Allura Xper R9*.

Configurations are composed of detector type, (monoplane) geometry, table type and available image processing. The monoplane (single C-arm) systems are categorized into X-ray systems and the configurations are differentiated by the following features:

- 12 inch Flat detector (FD12)
- 15 inch Flat detector (FD15)
- 20 inch Flat detector (FD20)

Additionally, identical to the predicate devices, all configurations of the **Allura Xper R9** are compatible for use in a hybrid operating room when supplied with a compatible operating room table, and can be optionally equipped with the ClarityIQ image processing algorithms.

Indications for Use: *The Allura Xper R9 series (within the limits of the used Operating Room table) are intended for use to perform:*

• Image guidance in diagnostic, interventional and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular and neuro procedures.

• Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.

Additionally:

• The Allura Xper R9 series can be used in a hybrid Operating Room.

• The Allura Xper R9 series contain a number of features to support a flexible and patient centric procedural workflow.

Patient Population:

All human patients of all ages. Patient weight is limited to the specification of the patient table.

Based on the information provided above, the **Allura Xper R9** is considered substantially equivalent to the currently marketed and predicate device *Allura Xper R9* in terms of Indications for Use.

Technological characteristics:

The **Allura Xper R9** has similar technological characteristics compared to the predicate device. The same hardware and software is used in the predicate and subject device. The only exception is the modification implemented in the **Allura Xper R9** which is:

- Addition of (optional) Quantitative Analysis feature by implementing 2D Quantitative Analysis software.

The 2D Quantitative Analysis software is unchanged from the reference device (clearance K161839 (July 29, 2016)).

See also table below:

Main system modules and components	Proposed Allura Xper R9 systems compared with the predicate device.
Acquisition	
X-ray generator	No change
Digital Flat Detector	No change
Flat Detector Controller	No change
X-Ray tube	No change
Beam limiting device	No change
Anti-scatter grid	No change
Patient & Beam Positioning	
Patient support	No change
Frontal stand	No change
Lateral stand	No change
User interfaces	
User interface modules	No change
Graphical user interfaces (GUI)	No change
Monitors	No change
Monitor ceiling suspension	No change
Infrastructure	
Cabinets	No change
PC’s	No change
Power distribution	No change
Video distribution	No change
Network	No change
System software	
System software	No change

Quantative analysis	
Quantitative Analysis functionality	Implementation of 2D Quantitative Analysis SW

The differences between the **Allura Xper R9** and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) submission, the **Allura Xper R9** is considered substantially equivalent to the currently marketed predicate *Allura Xper R9* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the **Allura Xper R9** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance documents:

- IEC 62304 *Medical device software – Software life cycle processes* (Edition 1.0, 2006). FDA/CDRH recognition number 13-32.
- ISO 14971 *Medical devices – Application of risk management to medical devices* (Edition 2.0, corrected version, 2007). FDA/CDRH recognition number 5-40.
- IEC 60601-2-28 - *Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis* (Edition 2.0, 2010). FDA/CDRH recognition number 12-204
- IEC 60601-2-43 - Particular requirements for the safety of X-Ray equipment for interventional procedures (Edition 2.0, 2010). FDA/CDRH recognition number 12-202.
- Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005 (document number 337).
- FDA Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices (document number 644).

Software verification testing of the functional and non-functional requirements as well as performance, reliability and safety has been performed to cover system level requirements as well as risk control measures. Results demonstrated that all executed tests were passed.

Non-clinical validation testing has been performed to cover the intended use, commercial claims, service, user needs, effectiveness of safety measures and instructions for use.

Therefore, **Allura Xper R9** is substantially equivalent to the currently marketed *Allura Xper R9* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The **Allura Xper R9** did not require clinical study data since substantial equivalence to the currently marketed predicate device *Allura Xper R9* was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

These attributes demonstrated that the clinical performance of the modified device is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion:

The **Allura Xper R9** is substantially equivalent to the currently marketed predicate device *Allura Xper R9* in terms of indications for use, technological characteristics and safety and effectiveness.

The modification of the **Allura Xper R9** is within the controls and predetermined specifications. Additionally, non-clinical performance tests provided in this 510(k) premarket notification demonstrated substantial equivalence to the predicate device and ensured that the modification is properly introduced; verification and validation testing was conducted to ensure the proper introduction of the modification listed; conformance to IEC standards and guidance documents were provided. All of these components and tests were used to support substantial equivalence of the subject device and demonstrate that the **Allura Xper R9** is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.