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

November 22, 2017

Re: K172822
Trade/Device Name: Azurion series R1.2
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: November 3, 2017
Received: November 6, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172822

Device Name
Azurion series R1.2

Indications for Use *(Describe)*

The Azurion series (within the limits of the used Operation 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 Azurion series can be used in a hybrid Operation Room.
• The Azurion 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:	September 13, 2017	
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/ +31 621823383 E-mail: jeanette.becker@philips.com	
Secondary Contact Person:	Ms. Marta Walker Senior Regulatory Affairs Manager Phone: +31 631978546 E-mail: marta.walker@philips.com	
Device:	Trade Name:	**Azurion series R1.2**
	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:	K163715 (January 26, 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:	*Allura Xper R8.2.1*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K141979 (August 19, 2014)
	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

Device description: The **Azurion series R1.2** is classified as an interventional fluoroscopic X-ray system. The primary performance characteristics of the **Azurion series R1.2** 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 **Azurion series R1.2** 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) and biplane (dual 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 **Azurion series R1.2** can be used 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 Azurion series R1.2 (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 Azurion series R1.2 can be used in a hybrid Operating Room.

• The Azurion series R1.2 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 **Azurion series R1.2** is considered substantially equivalent to the currently marketed and predicate device *Allura Xper R9* in terms of Indications for Use.

Technological characteristics:

The **Azurion series R1.2** has similar technological characteristics compared to the predicate device. The same hardware and software is used in the predicate and subject device. With exception of the following modifications implemented in the **Azurion series R1.2**:

- Commercial introduction of monoplane configurations with
  - 12" flat detector
  - 15" flat detector
- Flat detector controller and System interface box integrated in 1 (one) unit (FDC-SIB)
- Redesign of Power Distribution Unit (PDU)
- System Software with Support of new HW components mentioned above, FDCSIB and PDU. Support of new labeling.
- New Product name **Azurion**
- System software product maintenance
- Commercial introduction of bi-plane configurations
  - frontal 12" and lateral 12" flat detector
  - frontal 20" and lateral 12" flat detector
  - frontal 20" and lateral 15" flat detector

The differences between the **Azurion series R1.2** 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 **Azurion series R1.2** 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 **Azurion series R1.2** 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, **Azurion series R1.2** is substantially equivalent to the currently marketed *Allura Xper R9* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The **Azurion series R1.2** 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 **Azurion series R1.2** 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 **Azurion series R1.2** 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 modifications 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 **Azurion series R1.2** is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.