Philips Medical Systems Nederland BV
% Ms. Michelle Campbell
Regulatory Affairs Specialist
Veenpluis 4-6
Best, 5684PC
NETHERLANDS

May 1, 2020

Re: K200917
Trade/Device Name: Azurion R2.1
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: April 2, 2020
Received: April 6, 2020

Dear Ms. Campbell:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K200917

Device Name

Azurion R2.1

Indications for Use *(Describe)*

The Azurion series (within the limits of the 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:	April 2nd 2020	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Michelle Campbell Regulatory Affairs Officer Phone: +31 618345786 E-mail: michelle.campbell@philips.com	
Secondary Contact Person:	Michael Konings Director of Regulatory IGT Systems Phone: +31 619864032 E-mail: michael.konings@philips.com	
Device:	Trade Name:	**Azurion R2.1**
	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:	*Azurion R1.2*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K172822 (November 22, 2017)
	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
Secondary Predicate Device	Trade Name:	*Azurion R2.0*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K181830 (August 02, 2018)

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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 R2.1** is classified as an interventional fluoroscopic X-ray system. The primary performance characteristics of the **Azurion R2.1** 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 R2.1** is available in comparable models and configurations as the currently marketed and predicate device *Azurion R1.2*.

Configurations are composed of detector type (monoplane and biplane), floor or ceiling mounted geometry, standard or OR table type and available image processing. The FlexArm option is available for the 7M20 configuration in **Azurion R2.1** The monoplane (single C-arm) and biplane (dual arm) X-ray system 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 device, **Azurion R2.1** 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 (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 can be used in a hybrid Operating Room.

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• *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.

Based on the information provided above, the **Azurion R2.1** is considered substantially equivalent to the currently marketed and predicate device *Azurion R1.2* in terms of Indications for Use.

Technological characteristics:

The **Azurion R2.1** 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 R2.1**:

- Multi Modality Touch Screen Module which is an incremental development of the current Touch Screen Module
- Replacement of Windows 7 with Windows 10 OS
- An update of the graphics boards in all PCs
- Introduction of the Pixium 2121S detector as an alternative 12" detector for monoplane systems
- Inclusion of an optical imaging system within the FD20 detector outer frame. This option will not be enabled until the relevant application becomes available.
- The next release of the Certeray generator (Certeray release 5)
- The next release of the Poly-G geometry (Poly-G3)
  Extension of the Nicol V4 collimator for the Poly-G3 geometry (already introduced by release R2.0 for FlexArm options)
- Extension of the range with the introduction of additional Azurion 5 configurations
- Field feedback and minor updates from earlier releases

The differences between the **Azurion R2.1** and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) submission, **Azurion R2.1** is considered substantially equivalent to the currently marketed predicate *Azurion R1.2* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the **Azurion R2.1** 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 1.1, 2015-06). FDA/CDRH recognition number 13-79.
- ISO 14971 *Medical devices – Application of risk management to medical devices* (Edition 2.0, corrected version 2007-10-01). 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 3.0, 2017-06). FDA/CDRH recognition number 12-309.

- IEC 60601-2-43 - *Particular requirements for the safety of X-Ray equipment for interventional procedures* (Edition 2.0, 2010-03).
- *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).*
- *"Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", July 28, 2014 (document number 1766).*
- *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*

Software verification testing of the functional and non-functional requirements as well as performance, reliability and safety has been performed to verify that all the requirements of System Requirements Specification as well as the safety risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements have been implemented. Results demonstrated that all executed verification tests were passed.

Non-clinical validation testing has been performed to validate that **Azurion R2.1** conforms to the intended use, claims, user and service needs, effectiveness of safety measures and instructions for use. The validation consisted of the following activities:

Usability validation was performed with both interventional radiologists / cardiologists (physicians) and nurse/technicians in a simulated use environment. **Azurion R2.1** was found to be safe and effective for the intended use, users and use environment.

A simulated use design validation was undertaken with participants who fulfill the intended user profile. The participants executed validation protocols in the form of a clinical workflow to validate user needs, intended use, claims and effectiveness of the safety and instructions for use. Results demonstrated that all executed validation protocols were passed.

All these tests were used to support substantial equivalence of the subject device and demonstrate that **Azurion R2.1**:

- complies with the above-mentioned international and FDA-recognized consensus standards and FDA guidance documents, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, **Azurion R2.1** is substantially equivalent to the currently marketed *Azurion R1.2* in terms of safety and effectiveness.

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Summary of Clinical Performance Data:

The **Azurion R2.1** did not require clinical study data since substantial equivalence to the currently marketed predicate device *Azurion R1.2* 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 R2.1** is substantially equivalent to the currently marketed predicate device *Azurion R1.2* in terms of indications for use, technological characteristics and safety and effectiveness.

The modification of the **Azurion R2.1** is within the controls and predetermined specifications. Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that **Azurion R2.1** complies with the user need requirements as well as the requirements specified in the FDA-recognized consensus standards and guidance documents.

Therefore **Azurion R2.1** is as safe and effective as its predicate device and does not raise any new safety and/or effectiveness concerns.