October 24, 2025

Philips Medical Systems Nederland B.V.
℅ Rithika Gidijala
Regulatory Affairs Specialist
Veenpluis 6
Building QP
BEST, NOORD-BRABANT 5684PC
NETHERLANDS

Re: K251827
Trade/Device Name: Azurion R3.1
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: September 19, 2025
Received: September 19, 2025

Dear Rithika Gidijala:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251827

Device Name
Azurion R3.1

Indications for Use *(Describe)*
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.
• 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary

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

| | |
|---|---|
| **Date Prepared** | October 24, 2025 |
| **Submitter/Owner** | Philips Medical Systems Nederland B.V.<br>Veenpluis 6<br>5684 PC Best<br>The Netherlands<br>Establishment Registration Number: 3003768277 |
| **Primary Contact Person** | Rithika Gidijala<br>Regulatory Affairs Specialist, IGT-S Fixed<br>Phone: +1 8863334246<br>E-Mail: Rhitika.gidijala@philips.com |
| **Secondary Contact Person** | Daniela Zaczek<br>Director of Regulatory Affairs, IGT-S Fixed<br>Phone: +1 8863334246<br>E-Mail: Daniela.zaczek@philips.com |

### 1.1 Device

| | |
|---|---|
| **Trade Name** | Azurion R3.1 |
| **Common Name** | Azurion |
| **Classification Name** | Image-Intensified Fluoroscopic X-Ray System |
| **Classification Regulation** | 21 CFR §892.1650 |
| **Classification Panel** | Radiology |
| **Device Class** | Class II |
| **Product Code** | Primary Code: OWB<br>Subsequent Code: JAA |

### 1.2 Predicate Device

| **Predicate Device** | ***510(k) No.*** | ***Company Name***<br>***Device Name*** | ***Product Code*** |
|---|---|---|---|
| | *K200917* | *Philips Medical Systems Nederland B.V.*<br>*Azurion R2.1* | *Primary Code: OWB*<br>*Subsequent Code: JAA* |

## 1.3 Device Description

The **Azurion R3.1** is classified as an interventional fluoroscopic X-Ray system. The primary performance characteristics of the **Azurion R3.1** 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 with hospital information systems (HIS) and image archiving systems via DICOM
- Built in radiation safety controls

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

The **Azurion R3.1** is available in identical models and configurations as the predicate device *Azurion R2.1.* Configurations are composed of detector type, monoplane (single C-arm) or biplane (dual arm), floor or ceiling mounted geometry, standard or OR table type and available image processing. Identical to the predicate device, the FlexArm option is available for the 7M20 configuration in Azurion R3.1 to increase flexibility in stand movement**.**
Additionally, identical to the predicate device, **Azurion R3.1** can be used in a hybrid operating room when supplied with a compatible operating room table.

## 1.4 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.
- 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.

The indications for use of **Azurion R3.1** are the same as the indications for use of the predicate device *Azurion R2.1.* Based on the information provided below, **Azurion R3.1** is considered substantially equivalent to the predicate device *Azurion R2.1* in terms of Indications for Use.

## 1.5 Technological Characteristics

**Azurion R3.1** has similar technological characteristics compared to the predicate device. Similar features are used in the predicate and subject device, with the exception of the following modifications implemented in **Azurion R3.1**:

1. Redesign of Foot switch
2. Introduction of Instructions for Use (IFU) addendum for the wireless and wired foot switch and patient table – 'Reset Geo'.
3. Updated motion drives in Clea stand and AD7X patient table.
4. FlexVision Changes:
    - Introduction of 55" and 65" monitors
    - Resize Screen: software feature that can hide the top bar and viewport headers on the FlexVision monitor. This allows for more screen real estate to be used for the content in the viewports.
    - Additional FlexVision layout option
5. Trace Tools:
    - Color Trace: software feature that creates a color image using existing Digital Subtraction Angiography (DSA) gray scale series
    - View Trace function available on Multi-Modality Touch Screen Module non-graphical user interface module
6. Other minor software improvements:
    - Optimization of EPX database to reduce X-Ray tube wear
    - Event logs related to patient database size added to system startup
    - Extension of supported DICOM attributes
    - Windows OS security patches
    - Fixes to address field feedback and defects from previous releases

The differences between **Azurion R3.1** and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided, **Azurion R3.1** is considered substantially equivalent to the predicate device *Azurion R2.1* in terms of fundamental scientific technology.

## 1.6 Summary of Non-Clinical Performance Data

Non-clinical performance testing has been performed on **Azurion R3.1** and demonstrates compliance with the following International and FDA recognized consensus standards:

- IEC 60601-2-43 Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures, Edition 2.2 2019-10, Recognition Number 12-329.
- IEC 60601-2-28 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis, Edition 3.0 2017, Recognition Number 12-309.

- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests, Edition 4.1 2020, Recognition number 19-36.
- IEC TS 60601-4-2 Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance medical electrical equipment and medical electrical systems, Edition 1.0 2024, Recognition Number 19-50.
- IEC 62366-1 Medical devices - Part 1: Application of Usability Engineering to Medical Devices, Edition 1.1 2020, Recognition number 5-129.
- IEC 62304 Medical device software – Software life cycle processes, Edition 1.1 2015, Recognition number 13-79.
- ISO 14971 Medical devices – Application of risk management to medical devices, Edition 3.0 corrected version 2019, Recognition number 5-125.
- IEC 61910-1 Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy, Edition 1.0 2014, Recognition Number 12-290.
- NEMA XR-27 X-ray equipment for interventional procedures – User quality control mode, Edition 1.1 Amendment 1-2013, Recognition Number 12-286.
- ISO 15223-1 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements, Fourth edition 2021-07, Recognition Number 5-134.
- ISO 20417 Medical devices - Information to be supplied by the manufacturer, First edition 2021-04 Corrected version 2021-12, Recognition Number 5-135.
- ISO 17664-2 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices, First edition 2021-02, Recognition Number 14-579.
- IEC 60601-2-54 Medical Electrical Equipment- Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy, Edition 1.1 2009 + A1:2015 + A2:2018.
- IEC 60601-1-3 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment, Edition 2.1 2008 + A1:2013.
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Edition 3.1 2005 + C1:2006 + C2:2007 + A1:2012.
- IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability, Edition 3.1 2010 + A1:2013.
- DICOM Edition 2023.
- 21CFR Subchapter J 1020.30 Diagnostic x-ray systems and their major components.
- 21CFR Subchapter J 1020.32 Fluoroscopic equipment.

**Azurion R3.1** conforms to the following U.S. FDA guidance documents, which have been interpreted and applied in the preparation of the submission file:

- "Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Staff" (issued on June 14, 2023).

- "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (issued on June 27, 2025).

Non-clinical verification testing of the functional and non-functional requirements as well as performance, reliability and safety has been successfully performed to verify that all the requirements of System Requirements Specification as well as the safety risk control measures from the Risk Management Matrix have been implemented.

Non-clinical validation testing has been performed to validate that Azurion R3.1 conforms to the intended use, claims, user needs, effectiveness of safety measures and instructions for use. The validation consisted of the following activities:

- A simulated use design validation was undertaken with participants who fulfilled the intended user profile. The participants executed validation protocols in the form of a clinical workflow to validate user needs, intended use and claims. In addition, simulated use validation for service workflows was performed by a service engineer to validate specific service-related user needs. Results demonstrated that all executed simulated use validation protocols were passed.
- Usability validation was performed with representative clinical users (both physicians and nurse/technicians) in a simulated use environment. **Azurion R3.1** was found to be safe and effective for the intended use, users and use environment.

All these tests were used to support substantial equivalence of the subject device and demonstrate that Azurion R3.1:

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

Therefore, Azurion R3.1 is substantially equivalent to the predicate device *Azurion R2.1* in terms of safety and effectiveness.

## 1.7 Summary of Clinical Performance Data

The proposed Azurion R3.1 did not require clinical study since substantial equivalence to the predicate device *Azurion R2.1* was demonstrated with the following attributes:

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

## 1.8 Substantial Equivalence Conclusion

Azurion R3.1 is substantially equivalent to the predicate device *Azurion R2.1* (K200917) in terms of indications for use, technological characteristics and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that Azurion R3.1 complies with the system level requirements, user needs and international and FDA-recognized consensus standards, and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.