April 28, 2025

Shanghai United Imaging Healthcare Co.,Ltd.
℅ Xin Gao
Regulatory Affairs Manager
No.2258 Chengbei Rd. Jiading District
SHANGHAI, 201807
CHINA

Re: K243376
Trade/Device Name: uAngio AVIVA CX
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: October 28, 2024
Received: March 18, 2025

Dear Xin Gao:

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,

Lu Jiang

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)*
K243376

Device Name
uAngio AVIVA CX

Indications for Use *(Describe)*
The system is used to perform image guidance in diagnostic, intervention and surgical procedures. Procedures that can be performed with the system include cardiac angiography, neuro-angiography, vascular and non-vascular angiography, rotational angiography and whole body radiographic/fluoroscopic procedures.

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
K243376

1. **Date of Preparation:**
October 21, 2024

2. **Sponsor Identification**

Shanghai United Imaging Healthcare Co.,Ltd.
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3. **Identification of Proposed Device**

Trade/Device Name: uAngio AVIVA CX
Common Name: Interventional Fluoroscopic X-ray system
Model(s): uAngio AVIVA CX

Regulatory Information
Classification Name: Image-intensified fluoroscopic x-ray system
Classification: II
Product Code: Primary Code: OWB
Subsequent Code: JAA
Regulation Number: 21 CFR 892.1650
Review Panel: Radiology

4. **Identification of Predicate Device(s)**

Predicate Device

Trade/Device Name: Azurion R2.1
510(k) Number: K200917
Manufacturer: Philips Medical Systems Nederland B.V.

Regulatory Information
Classification Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1650
Review Panel: Radiology
Device Class: Class II

Product Code: Primary Code: OWB
Secondary product Code: JAA

Reference Device #1:

Trade/Device Name: SmartCT
510(k) Number: K201583
Manufacturer: Philips Medical Systems Nederland B.V.

Regulatory Information
Classification Name: Interventional fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1650
Review Panel: Radiology
Device Class: Class II
Product Code: Primary Code: OWB
Subsequent Codes: JAK, LLZ

5. Device Description

The uAngio AVIVA CX is an angiographic X-ray system that generates X-rays through the X-ray tube, receives the signal through the flat panel detector and presents the image after D/A conversion and image post-processing.
The uAngio AVIVA CX is designed to provide intelligent, safe, and precise image guidance in cardiac, neuro, oncology, peripheral interventional, and surgical procedures.
The main components of the uAngio AVIVA CX include a C-arm stand, patient table, generator, X-ray tube, flat panel detector, collimator, grid, monitors, control module, control panel, foot switch, hand switch, V-box, and intercom.
The main software characteristics of the uAngio AVIVA CX include patient registration, patient administration, 2D&3D image viewing and post-processing, data import/archiving, filming, camera-assisted recognition function (uSpace), and voice control function (uLingo).

6. Indications for use

The system is used to perform image guidance in diagnostic, intervention and surgical procedures.
Procedures that can be performed with the system include cardiac angiography, neuro-angiography, vascular and non-vascular angiography, rotational angiography and whole body radiographic/fluoroscopic procedures.

7. Comparison of Technological Characteristics with the Predicate Devices

A comparison between the technological characteristics of the proposed and predicate device and reference devices is provided as below.

ITEM	Proposed Device: uAngio AVIVA CX	Predicate Device: Azurion R2.1(K200917)	Remark
Classification Name	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Same
Classification Regulation	21 CFR, Part 892.1650	21 CFR, Part 892.1650	Same
Classification Panel	Radiology	Radiology	Same
Device Class	II	II	Same
Product Code	OWB, JAA	OWB, JAA	Same
Indications for Use	The system is used to perform image guidance in diagnostic, intervention and surgical procedures. Procedures that can be performed with the system include cardiac angiography, neuro-angiography, vascular and non-vascular angiography, rotational angiography and whole body radiographic/fluoroscopic procedures.	The Azurion series (within the limits of the used operating room table) is 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 contains a number of features to support a flexible and patient-centric	Note1

		procedural workflow. Patient Population: All human patients of all ages. Patient weight is limited to the specification of the patient table.	
Specifications			
Generator			
Max. generator power	100 KW	100 KW	Same
Max. current	1000 mA at 100 kV	1000 mA at 100 kV	Same
X-ray tube			
Focal spot	0.4mm, 0.6mm, 1.0mm	0.4mm, 0.7mm	Note2
Continuous anode input power	3500W	3500W	Same
Flat panel detector-config.1			
Max. field of view	48 cm diagonal	48 cm diagonal	Same
Pixel pitch	154 μm	154 μm	Same
DQE (at 0lp/mm)	77%	77%	Same
Flat panel detector-config.2			
Max. field of view	48 cm diagonal	48 cm diagonal	Same
Pixel pitch	150 μm	154 μm	Note3
DQE (at 0lp/mm)	77%	77%	Same
Collimator	YES	YES	Same
Removable anti-scatter grid	YES	YES	Same
Stand			
longitudinal movement	Max. 6350 mm	Max. 6350 mm	Same

lateral movement range	Max. 2360 mm	Max. 2360 mm	Same
L-arm rotation	±135 °	±135 °	Same
Patient table - config.1 Floating table			
max. table load	340 kg	325 kg	Note4
max. patient weight	280 kg + 600 N for CPR CPR can be done in any position of the table top	250 kg + 500 N for CPR. CPR can be done in any position of the table top	Note5
Pivot	±180 °	- 90 °/+180 °or -180 °/+90 °	Note6
Patient table - config.2 Multi-tilt table			
max. table load	380 kg	325 kg	Note7
max. patient weight	280 kg + 600 N for CPR	250 kg + 500 N for CPR.	Note8
Pivot	±180 °	-90 °/+180 °or -180 °/90 °	Note9
tilt	+15 °, -20 °	±16.5 °	Note10
cradle	±15 °	±15 °	Same
Image acquisition protocol			
Fluoroscopy	YES	YES	Same
Roadmap	YES	YES	Same
Dynamic DR	YES	YES	Same
2D DSA	YES	YES	Same
Singleshot	YES	YES	Same
Cine	YES	YES	Same
Bolus Chase and Bolus Chase Reconstruction	YES	YES	Same

Protocol for Pediatric	YES	YES	Same
Software function			
Camera-assisted recognition (uSpace)	YES	NO	Note11
Voice control (uLingo)	YES	NO	Note12
Safety			
basic safety and essential performance	ANSI/AAMI ES60601-1:2005/A2:2021	IEC 60601-1, 2nd Ed. + Amendment No. 1 + Amendment No. 2 + Corrigendum	Same
Electro Magnetic Compatibility	ANSI/AAMI/IEC 60601-1-2:2014/A1:2021	IEC 60601-1-2, ed.2.1	Same

ITEM	**Proposed Device: uAngio AVIVA CX**	**Reference Device: SmartCT R1.0(K201583)**	**Remark**
3D rotational angiography	YES	YES	Same
Cone Beam CT (CBCT)	YES	YES	Same
High-resolution Cone Beam CT	YES	YES	Same
3D Roadmap	YES	YES	Same

Justification	
Note1	In general, both products are used to perform image guidance in diagnostic, interventional, and surgery procedures, and are suitable for all human patients of all ages. The description differences between the two products do not affect safety and effectiveness.

Note2	uAngio AVIVA CX has one more focal spot than the predicate device. Even if one focal filament fails, the others remain operational, and the drive circuits for all three focal filaments are independent. The difference does not introduce safety and effectiveness issues.
Note3	The smaller the pixel pitch, the greater the capability to capture fine structures, which means the ability to identify smaller lesions and tissues. The difference does not introduce safety and effectiveness issues.
Note4	The patient table (config.1 Floating table) of the proposed device has a higher weight capacity, meeting the needs of more clinical scenarios. The difference does not introduce safety and effectiveness issues.
Note5	The patient table (config.1 Floating table) of the proposed device has a higher patient weight capacity, enabling it to serve a broader patient population. The difference does not introduce safety and effectiveness issues.
Note6	The patient table (config.1 Floating table) of the proposed device has a larger rotation range, meeting the needs of more clinical scenarios. The difference does not introduce safety and effectiveness issues.
Note7	The patient table (config.2 Multi-tilt table) of the proposed device has a higher weight capacity, meeting the needs of more clinical scenarios. The difference does not introduce safety and effectiveness issues.
Note8	The patient table (config.2 Multi-tilt table) of the proposed device has a higher patient weight capacity, enabling it to serve a broader patient population. The difference does not introduce safety and effectiveness issues.
Note9	The patient table (config.2 Multi-tilt table) of the proposed device has a larger rotation range, meeting the needs of more clinical scenarios. The difference does not introduce safety and effectiveness issues.
Note10	The patient table (config.2 Multi-tilt table) of the proposed device has a broader total tilt range than that of the predicate device. The difference does not introduce safety and effectiveness issues.
Note11	uSpace uses multi-view cameras with machine learning methods and includes the following features: 1. uSpace Auto Positioning: it allows users to send a specific body part of the patient to the system and automatically position it by long-pressing a button. 2. uSpace VeraCT: it allows users to skip the process of conventional AP and lateral positioning and Test Run during the VeraCT acquisition, and get to the acquisition start point only by long-pressing one button.3. uSpace Auto SID: adjust the SID within a certain range to make it closer to the patient's surface. 4. uSpace Auto Parameter: reduce the process of parameters setting based on the patient's actual body thickness. 5. uSpace Iso Tracking: adjust the table height to align the patient’s isocenter with the C-arm isocenter. System motion is initiated only by the user's continuous triggering and the system is equipped with hardware-based collision prevention features to ensure safety. The difference does not introduce safety and effectiveness issues.

Note12	uLingo is based on a machine learning method and it allows the system to be controlled via user's voice command, such as protocol selection, image browsing, motion control, and tool utilization, to enhance the system's usability. uLingo will not directly trigger radiation or motion. The system provides voice confirmation/feedback for the functions related to radiation and motion, for example motion lock/unlock, radiation lock/unlock, protocol selection, motion control, etc. The difference does not affect safety and effectiveness.

8. Performance Data

Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

[1]. ANSI/AAMI ES60601-1:2005/A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2
[2]. ANSI/AAMI/IEC 60601-1-2:2014/A1:2021 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests - Amendment 1
[3]. IEC 60601-1-3:2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
[4]. IEC 60601-2-54:2022 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
[5]. IEC 60601-2-43：2022 Medical Electrical Equipment - Part 2-43: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Interventional Procedures
[6]. IEC 60601-2-28:2017 Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
[7]. IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements

Additional non-clinical tests are conducted for each key feature to ensure safe and effective integration into the system:

Feature	Bench Testing Performed
Cone Beam CT	The bench tests evaluate the performance of CBCT. The objectives of the tests are to demonstrate: i. C-arm positioning accuracy; ii. Imaging performance of CBCT (including in-plane uniformity, spatial resolution, reconstruction section thickness, noise, contrast to noise ratio, artifact analyses) can meet the requirements. iii. Radiation dose can meet the requirements. The geometric phantom, Catphan700 phantom, chest phantom, head phantom, CTDI dosimetry phantom, body phantom and head phantom are used in the tests above. The test results show:

	- The position error of the C-arm is acceptable and the position is repeatable. - The imaging performance of CBCT fulfills the requirements. - CTDI of CBCT protocols fulfills the requirement. Note: CBCT images are not for quantitative use.
Fusion	The tests evaluate the performance of the Image Registration Algorithm. The objectives of the tests are to demonstrate: - The accuracy of the Image Registration Algorithm can meet the requirement of mean target registration error (mTRE) less than the pixel diagonal distance. The test results show: - Using DSA mask to regist with DSA mask, CBCT, CT, CTA, and MR for testing image registration. Each group has three sets of test data. - All the mTREs of the test cases are smaller than the voxel diagonal distance, which can achieve sub-pixel accuracy registration. Image Registration Algorithm is able to meet the verification criteria, the verification result is passed.
DSA	The tests evaluate the performance of the DSA Algorithm. The objectives of the tests are to demonstrate: Dynamic range meets the submillimeter vessel simulation component is visible across all copper step wedges of the subtracted image. Contrast sensitivity meets the low millimeter vascular simulation component should be visible in a copper step wedge of sufficient thickness in the subtraction image. The test results show: Using digital subtraction angiography phantom with compensation test step wedge to test subtracted image of DSA，four typical groups（Body，Head，Vascular，Pediatric） are tested ,each group applying two sets of test data. From the testing results, submillimeter sized blood vessels can be seen in all copper step wedges, and the thickness of blood vessels visible in sufficiently thick copper step wedges meets the requirements.
3D Roadmap	The tests evaluate the performance of Neuro Registration Algorithm. The objectives of the tests are to demonstrate: - The accuracy of neuro registration can meet a precision of at least 1 mm. The test results show: - Using 3D DSA mask to register with an FL image for testing neuro registration. It has eight sets of test data in the group.

	- The registration results of neuro registration algorithm is that the mTRE is less than 1mm. The neuro registration was able to meet a precision of at least 1 mm, the verification was passed.
uChase	The tests evaluate the performance of the Stitching Algorithm. The objectives of the tests are to demonstrate: - The accuracy of the Image Registration Algorithm in Stitching can meet the requirement of mean target registration error (mTRE) less than the pixel diagonal distance. - The stitching results meet the clinical needs, with an average score from clinical specialists higher than 2. The test results show: - All the mTREs of the test cases are smaller than the pixel diagonal distance, and the average score of stitching results is 2.95, which is higher than 2.The Stitching Algorithm was able to meet the verification criteria and the verification of the algorithm was passed.
uSpace	The tests evaluate the performance of uSpace futures. The objectives of the tests are to demonstrate: - Test the performance of the human key point detection accuracy. - Test the performance of the collision detection rate. - The performance of the auto SID meets the distance maintenance accuracy. And the adjustment of SID meets the requirements of radiation safety and image quality. The test results show: - Human key point detection achieves the required accuracy for not deviating from the range of the acquisition field of view. - Collision detection achieves the specified detection rate. - Auto SID adjustment achieves the required accuracy for maintaining a distance from detector to the patient during C-arm rotation or patient table lifting. Primary protective barrier, Field limitation and Air kerma rates were tested within the allowable adjustment range of the system. The radiation safety test results of the uAngio AVIVA CX under different SID. The image quality evaluation was tested through the clinical evaluation and objective physical characteristics. According to the acceptable criteria in the regulations, the image quality test results of the uAngio AVIVA CX under different SID meet the requirements.
uLingo	The tests evaluate the performance of the uLingo algorithm. The objectives of the tests are to demonstrate: - Test the performance of wake-up algorithm. - Test the performance of voice commands recognition algorithm.

	The test results show: For U.S. Participants, 18 talkers were invited to record the voice commands for verification. - The recognition rate of voice wake-up is tested as below: When the environmental signal-to-noise ratio (SNR) is ⩾15 dB(A), the wake-up accuracy rate reaches ⩾95%; When environmental SNR is 10 dB(A), the wake-up accuracy rate reaches ⩾85%. - The recognition rate of voice commands is tested as below: When the environmental SNR is ⩾15 dB(A), the recognition success rate for each command reaches ⩾95%; When the environmental SNR is 10 dB(A), the recognition success rate for each command reaches ⩾85%

Clinical Image Evaluation

The clinical image evaluation was performed under the proposed device. Sample images were obtained from hospitals to meet the following requirements: contained images of the head, cardiac, body, and extremities with different acquisition protocols representative of US clinical use and populations. Typical cases have been selected such as Internal carotid artery angioplasty and stenting, internal carotid artery stenosis and aneurysm, PCI, radiofrequency ablation, TACE, TIPS, lower extremity arterial angioplasty and so on. The image quality was evaluated by an ADR certified radiologist using a five-point scale, evaluation on image quality aspects: spatial detail, contrast-noise performance, clinical motion and clinical features of interest. Each image received a score of ⩾ 3 and received a PASS result, indicating that image quality fulfills the need for diagnostic, intervention, and surgical procedures.

9. Conclusion

Based on the comparison and analysis above, the proposed device uAnigo AVIVA CX has the equivalent intended use, safety, and effectiveness as the predicate device Philips Azurion R2.1 and the reference device SmartCT. The differences in technical specifications between the proposed device and the predicate device do not negatively affect the system's safety and effectiveness. The proposed device uAngio AVIVA CX is determined to be Substantially Equivalent (SE) to the predicate device and the reference device.