August 21, 2026

Shanghai United Imaging Healthcare Co., Ltd.
% Xin Gao
Regulatory Affairs Manager
2258 Chengbei Rd.
Jiading District
SHANGHAI, 201807
CHINA

Re: K253726
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: November 18, 2025
Received: November 24, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253726

Please provide the device trade name(s).

uAngio AVIVA CX

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510 (k) SUMMARY

1. Date of Preparation:

August 20, 2026

2. Sponsor Identification

Shanghai United Imaging Healthcare Co., Ltd.
No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Establishment Registration Number: 3011015597

Contact Person: Xin GAO
Position: Regulatory Affairs Manager
Tel: +86-021-67076888-5386
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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: uAngio AVIVA CX
510(k) Number: K243376
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

Reference Device #1:

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 #2:

Trade/Device Name: StentBoost Live
510(k) Number: K170144
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: 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), voice control function (uLingo), uStent & uStent Live, and VeraNF.

The proposed changes to the predicate device, uAngio AVIVA CX (K243376), include three newly added features: uStent, uStent Live, and VeraNF:

uStent: uStent is a feature that generates a stent-enhancement image, based on multi-frame X-ray images containing the stent. The feature identifies and tracks stent markers across frames and combines the aligned frames to produce a single image in which the stent is more clearly displayed.

uStent Live: uStent Live is a feature that provides a real-time stent-enhancement image in which the stent remains fixed within the field of view, based on a live stream of X-ray images. The feature identifies and tracks stent markers in real time and combines the current frame with previous frames to continuously generate an enhanced image with the stent remaining fixed within the field of view.

uStent and uStent Live are not intended for use in patients with a body mass index (BMI) $\geqslant$ 30 kg/m^2.

VeraNF: VeraNF is a deep learning-based denoising feature that processes raw image data to produce output images with a higher signal-to-noise ratio (SNR).

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: uAngio AVIVA CX (K243376)	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 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.	Same
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, 0.6mm, 1.0mm	Same

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	150 μm	Same
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	340 kg	Same
max. patient weight	280 kg + 600 N for CPR CPR can be done in any position of the table top	280 kg + 600 N for CPR CPR can be done in any position of the table top	Same
Pivot	±180 °	±180 °	Same
Patient table - config.2 Multi-tilt table			

max. table load	380 kg	380 kg	Same
max. patient weight	280 kg + 600 N for CPR	280 kg + 600 N for CPR	Same
Pivot	±180 °	±180 °	Same
tilt	+15 °, -20 °	+15 °, -20 °	Same
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	YES	Same
Voice control (uLingo)	YES	YES	Same
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

Azurion R2.1(K200917)

ITEM	Proposed Device: uAngio AVIVA CX	Reference Device#1: Azurion R2.1(K200917)	Remark
VeraNF	YES	YES	Same

Stentboost Live (K170144)

ITEM	Proposed Device: uAngio AVIVA CX	Reference Device#2: Stentboost Live (K170144)	Remark
uStent & uStent Live	YES	YES	Note 1

Justification	
Note 1	StentBoost Live is intended for use with the entire adult human population. uStent and uStent Live are only intended for use with the adult human population with a BMI less than 30 kg/m ²

8. Performance Data

Non-Clinical Testing

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

Feature	Bench Testing Performed
uStent&uStent Live	The tests evaluate the performance of the uStent and uStent Live algorithms. The test results show: - In uStent, the stent marker tracking success rate is greater than 90%. Success is defined as meeting all of the following conditions: no false-positive stent marker detections and detection of a stent marker pair (distance < 0.3 mm) in at least 20 out of 40 non-contrast frames. - In uStent Live, the proportion of successful marker detections for individual images is greater than 94.5%, using a pass/fail criterion that requires the distance between the detected stent marker position and its corresponding annotation to be less than 0.3 mm. - uStent's inference time for a 45-frame video is less than 5 seconds, and uStent Live's inference time is less than 3 seconds in the first stage and less than 45 ms per frame in the second stage. Both satisfy the clinical requirements. The peak GPU memory usage is less than 8GB, meeting the hardware requirement.
VeraNF	The image quality performance and patient entrance dose rate of VeraNF protocols fulfill the requirements. 1.Spatial resolution of VeraNF protocols: -For 'Fluoroscopy' mode, the testing results should be no less than 1.0 lp/mm, and the worst test result is 1.8 lp/mm. -For ‘Radiography’ mode, the testing results should be no less than 1.2 lp/mm, and the worst worst test result is 1.8 lp/mm 2.Low contrast resolution of VeraNF protocols: -For 'Normal Mode Fluoroscopy', the testing results should be no more than 5.6%, and the worst test result is 3.3%. -For 'Radiography' mode, the testing results should be no more than 2.8%, and the worst test result is 2.7%. 3. Dynamic range of VeraNF protocols: -For 'Pulse Fluoroscopy', 'Cine', and 'Dynamic Digital Radiography' mode, the testing results should be no less than 14 grey levels, and the worst test result is 15 grey levels. -For ‘Single Shot’ mode, the testing results should be no less than 16 grey levels, and the worst test result is 15 grey levels.

	-For 'Fluoroscopic Subtraction' mode, the testing results should ensure that the 0.4 mm vessel is visible across all copper step wedges, and the test results fulfill the requirements. -For 'Radiographic Subtraction' mode, the testing results should ensure that the 0.2 mm vessel is visible across all copper step wedges, and the test results fulfill the requirements. 4. Uniformity of VeraNF protocols: -Under the condition of flat plate correction, the image uniformity should be no more than 2.2%, and the worst test result is 1.63%. 5.Motion blur of VeraNF protocols: -At least the complete 0.016 inch line should be resolved, and the number of artifacts of the 0.022 inch line should be no more than 3. The test results show that the wire with 0.016 inch can be resolved and the maximum number of artifacts is three. 6. Contrast Sensitivity of VeraNF protocols: -For 'Fluoroscopic Subtraction' mode, the testing results should ensure that the 0.2mm vessel is visible within the 0.8mm copper step wedge, and the test results fulfill the requirements. -For 'Radiographic Subtraction' mode, the testing results should ensure that the 0.05mm vessel is visible within the 0.8mm copper step wedge, and the test results fulfill the requirements. 7. Patient Entrance Dose rate of VeraNF protocols: -The AKR should be no more than 88 mGy/min, and the highest test result is 38.79 mGy/min.

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 clinical image evaluation includes several studies:

VeraNF:

1. Systematic review of algorithm-generated "residual images."
2. Head-to-head comparison between the new and traditional algorithms on a representative dataset.
3. Clinical evaluation of full images generated by the VeraNF algorithm

uStent and uStent Live:

Clinical evaluation of enhanced images assessing stent/balloon clarity.

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 uAnigo AVIVA CX(K243376) and reference devices, Philips Azurion R2.1, and Stentboost Live. 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 devices.