May 12, 2025

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

Re: K243632
Trade/Device Name: uWS-Angio Basic
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 11, 2025
Received: April 11, 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)*
K243632

Device Name
uWS-Angio Basic

Indications for Use *(Describe)*
uWS-Angio Basic is intended to display and process XA (X-Ray Angiographic), CT (Computed Tomography), and MR (Magnetic Resonance) images that comply with the DICOM3.0 protocol.

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.

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510 (k) SUMMARY

1. Date of Preparation:

May 7, 2025

2. Sponsor Identification

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

Establishment Registration Number: 3011015597

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3. Identification of Proposed Device

Trade Name: uWS-Angio Basic
Common Name: Medical image management and processing system
Model(s): uWS-Angio Basic

Regulatory Information
Classification Name: Medical image management and processing system
Classification: II
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Review Panel: Radiology

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K230955
Device Name: Syngo Application Software

Secondary Predicate Device#1
510(k) Number: K183170

Device Name: uWS-CT

Secondary Predicate Device#2
510(k) Number: K232147
Device Name: CAAS Workstation

5. Device Description

uWS-Angio Basic is an image processing software that matches the use of medical vascular angiography X-ray machines. It contains the following functions:

- Patient Administration
- Review 2D: This application can be used to load 2D images and perform related processing. The function provides Basic processing tools for
  1) 2D image viewing,
  2) 2D image processing,
  3) 2D DSA image viewing and processing,
  4) Calibration and Measurement.
- Review 3D: This application can be used for loading and processing 3D data. The function provides Basic processing tools for
  1) 3D image viewing;
  2) 3D image processing;
  3) CTA bone removal.
- Saving
- Filming

uWS-Angio Basic can be deployed on independent hardware such as a stand-alone diagnostic review and post processing workstation. It can also be configured within a network to send and receive DICOM data. Furthermore, it can be deployed on systems of the United-imaging Angiography system family.

6. Indications for use

uWS-Angio Basic is intended to display and process XA (X-Ray Angiographic), CT (Computed Tomography), and MR (Magnetic Resonance) images that comply with the DICOM3.0 protocol.

7. Summary of Technological Characteristics

The proposed device uWS-Angio Basic and the predicate device syngo Application Software share similar indications for use: enabling the viewing and post-processing of medical images from angiography systems and other DICOM data through basic functions. Both devices are indicated for patients undergoing angiography and fluoroscopy-based procedures and are designed to support healthcare professionals in healthcare institution settings. The intended patient population and applicable clinical scenarios are the same for these two devices. The proposed device includes fewer applications compared to the predicate device. The difference does not raise different questions of safety and effectiveness

The following tables present a comparative analysis of the main features, principles of operation, fundamental scientific technology and intended use of the proposed device in relation to both predicate device and Secondary predicate devices.

Table 1 General information comparison

Item	Proposed Device uWS-Angio Basic	Predicate Device syngo Application Software (K230955)	Remark
General			
Device Classification Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Same
Product Code	LLZ	LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Device Class	II	II	Same
Classification Panel	Radiology	Radiology	Same

Table 2 Substantial equivalence discussion for uWS-Angio Basic functions

Item	Function name	Proposed device uWS-Angio Basic	Predicate device Syngo Application Software (K230955)	Secondary predicate device#1: uWS-CT (K183170)	Secondary predicate device#2: CAAS Workstation (K232147)	Remark
Patient Administration	Patient data display	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Searching, filtering, importing, archiving and modification of patient data	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
Review 2D	2D image viewing					
	Data loading and displaying	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	2D image processing					
	Invert	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Shutter	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Zoom/pan	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Windowing	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Flip	Yes	Yes	Yes	/	Same (Identical with uWS-CT)

	Annotation	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Enhance Edge	Yes	Yes	/	/	Same
	Synchronize series	Yes	/	/	/	Note1
	Reset & Undo	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Crop series	Yes	/	/	/	Note 2
	2D DSA image viewing and processing					
	Sub/unsub	Yes	Yes	/	Yes	Same
	Pixel shift	Yes	Yes	/	/	Same
	Anatomical background adjustment	Yes	Yes	/	/	Same
	Moving Mask	Yes	Yes	/	/	Same
	Maximum filled	Yes	Yes	/	Yes	Same
	Calibration					
	Isocenter calibration	Yes	Yes	/	Yes	Same
	Catheter calibration	Yes	Yes	/	Yes	Same
	Manual distance calibration	Yes	Yes	/	Yes	Same
	Sphere calibration	Yes	Yes	/	Yes	Same
	Measurement					
	Distance measurement	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Curve measurement	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Angle measurement	Yes	Yes	Yes	Yes	Same (Identical with uWS-CT)
	Ratio Calculation	Yes	/	/	Yes	Same
Review 3D	3D image viewing					
	Support volume rending (VR) and MPR image display	Yes	Yes	Yes	/	Same (Identical with uWS-CT)

	Switching display layout	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	3D image processing					
	Zoom	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	Pan	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	Windowing	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	Thickness adjustment	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	Rotate	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	Annotation	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	3D calculation	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	Cut	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	VOI extraction	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
	CTA bone removal	Yes	/	Yes	/	Same (Identical with uWS-CT)
Saving	Image/movie/bookmark saving	Yes	Yes	Yes	/	Same (Identical with uWS-CT)
Filming	Layout editing and printing	Yes	/	Yes	/	Same (Identical with uWS-CT)

Note 1: Compared to the predicate device and Secondary predicate devices, the proposed device adds Synchronize Series function. This function can synchronize double series, compare and view two series. This difference does not raise different questions of safety and effectiveness.

Note 2: Compared to the predicate device and Secondary predicate devices, the proposed device adds Crop Series function. This function can help user to eliminate unwanted images from a series. This difference does not raise different questions of safety and effectiveness.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
Not Applicable to the proposed device, because the device is stand-alone software.

Electrical Safety and Electromagnetic Compatibility (EMC)
Not Applicable to the proposed device, because the device is stand-alone software.

Software
Software verification and validation testing was provided to demonstrate safety and efficacy of the proposed device. This includes a hazard analysis, and the potential hazards to satisfy the recommended documentation for basic documentation. These documentations include:

- Software Description
- Device Hazard Analysis
- Software Requirements Specification (SRS)
- Software Architecture Design Chart
- Software Development Environment Description
- Software Verification and Validation
- Cybersecurity Documents

Animal Study
No animal study was required.

Clinical Studies
No clinical study was required.

Performance Testing
The algorithms involved in the uWS-Angio Basic are as follows:

- Catheter Calibration Algorithm for Review 2D
- CTA Removing Bone Algorithm for Review 3D

Testing was conducted between uWS-Angio Basic and the predicate device to evaluate the performance of the algorithms mentioned above. It is shown that catheter calibration of uWS-Angio Basic has high accuracy with average error rates consistently lower than those of the predicate device. CTA Removing Bone of the uWS-Angio Basic perform as well as the predicate devices.

Other Standards

- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2023e).
- ISO 14971 Medical devices - Application of risk management to medical devices (Third Edition 2019-12).
- IEC 62304 Medical device software - Software life cycle processes (Edition 1.1, 2015).

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above; the uWS-Angio Basic is found to have a safety and effectiveness profile that is similar to the predicate device and Secondary predicate devices.

9. Substantially Equivalent (SE) Conclusion

The proposed device is substantially equivalent to the predicate device. This conclusion is based upon a comparison of intended use, technological characteristics, performance specification, device hazards as well as verification and validation results.