September 12, 2025

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

Re: K250040
Trade/Device Name: uWS-Angio
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 6, 2025
Received: August 14, 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)*
K250040

Device Name
uWS-Angio

Indications for Use *(Describe)*
uWS-Angio is a post-processing software based on the uWS-Angio Basic for viewing, processing, evaluating and analyzing XA images. It has the following application:
- The uWS-Angio 2D Vessel Analysis is intended to provide users a tool for quantifying the dimensions of coronary and peripheral vessels from 2D angiographic images. It supports vessel segmentation and output associated diameter parameters and curves.
- The uWS-Angio Left Ventricular Analysis application is intended to provide users a tool for analyzing left ventricular functions. It supports editing contours of ventricular and outputs a set of parameters to show the ventricular functions and wall motion.
- The uWS-Angio 2D Blood Flow Analysis application is intended to provide users a tool for analyzing blood flow of region of interest in peripheral vessels. It supports adding interest region and output multiple blood flow parameters for further perfusion analysis.
- The uWS-Angio Stitching is intended to provide users a tool for lower extremities stitching bolus-chase acquired images into a stitching image.

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

1. Date of Preparation:

September 10, 2025

2. Sponsor Identification

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3. Identification of Proposed Device

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

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
Regulation Number: 892.2050
Product Code: LLZ

Reference Device#1
510(k) Number: K131299
Device Name: Anythink
Regulation Number: 892.2050
Product Code: LLZ

Reference Device#2
510(k) Number: K233186
Device Name: uOmnispace.MR
Regulation Number: 892.2050
Product Code: QIH, LNH

5. Device Description

uWS-Angio is a post-processing software intended for viewing, processing, evaluating, and analyzing medical images that comply with the DICOM 3.0 protocol. It supports interpretation and evaluation of examinations within healthcare institutions. It 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 Healthcare Angiography system family.

uWS-Angio contains the following applications:
- uWS-Angio 2D Vessel Analysis
- uWS-Angio Left Ventricular Analysis
- uWS-Angio 2D Blood Flow Analysis
- uWS-Angio Stitching

6. Indications for use

uWS-Angio is a post-processing software based on the uWS-Angio Basic for viewing, processing, evaluating and analyzing XA images. It has the following application:

- The uWS-Angio 2D Vessel Analysis is intended to provide users a tool for quantifying the dimensions of coronary and peripheral vessels from 2D angiographic images. It supports vessel segmentation and output associated diameter parameters and curves.

- The uWS-Angio Left Ventricular Analysis application is intended to provide users a tool for analyzing left ventricular functions. It supports editing contours of ventricular and outputs a set of parameters to show the ventricular functions and wall motion.
- The uWS-Angio 2D Blood Flow Analysis application is intended to provide users a tool for analyzing blood flow of region of interest in peripheral vessels. It supports adding interest region and output multiple blood flow parameters for further perfusion analysis.
- The uWS-Angio Stitching is intended to provide users a tool for lower extremities stitching bolus-chase acquired images into a stitching image.

7. Summary of Technological Characteristics

The technology characteristics of the proposed device reflected in this 510(k) submission are substantially equivalent to those of the predicate device and reference devices.

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 reference devices

Table 1 General information comparison

Item	Proposed Device uWS-Angio	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
Advanced Application	Yes	Yes	Same

The proposed device uWS-Angio and the predicate device syngo Application Software share similar indications for use: providing image viewing and post processing. 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 will not impact the safety and effectiveness of the subject device. Therefore, the proposed device can be considered substantially equivalent to the predicate device in terms of Indications for Use.

Table 2 Substantial equivalence discussion for uWS-Angio applications

Application	Function name	Proposed device uWS-Angio	Predicate device Syngo Application Software (K230955)	Reference Device#1 Anythink (K131299)	Reference device#2 uOmnispace.MR (K233186)	Remark
2D Vessel Analysis	**Vessel contour extraction**	Yes	Yes	/	/	Note 1
	Contour editing	Yes	Yes	/	/	Note 1
	Stenosis analysis	Yes	/	Yes	/	Same
Left Ventricular Analysis	Outlining and editing contour	Yes	/	Yes	/	Same
	Left ventricular volume calculation: **- ejection fraction** **- diastolic volume** **- systolic volume** **- stroke volum**e	Yes	/	Yes	/	Same
	Wall motion analysis	Yes	/	Yes	/	Same
2D Blood Flow Analysis	**ROI related functions:** **- ROI markers** **- ROI parameter result display** **- ROI corresponding**	Yes	Yes	/	/	Note 2

	TDC curve display - Export curve to csv file					
	Pseudo-Color Chart Comparison Display	Yes	Yes	/	/	Same
Stitching	Automatic stitching	Yes	/	/	Yes	Note 3

Note 1：Compared to the predicate device, the Vessel contour extraction and Contour editing functions of 2D Vessel Analysis application of the proposed device is the substantially equivalent to the QCA and QVA of the predicate device. The difference doesn't impact the safety and effectiveness of the subject device.

Note 2: Compared to the predicate device, the proposed device provides additional parameters: Arrival time, Wash-in Rate, Width, Mean Transit Time, Rise Time. These parameters are mathematically calculated based on the shape of the time-density curve. The differences don't impact the safety and effectiveness of the subject device.

Note 3：Compared to the reference device#2, the proposed device has the same auto stitching function. The input for the proposed device is DSA bolus-chase series, and the input for reference device#4 is MR series. Both input data are compliance with DICOM 3.0 standard. The difference doesn't impact the safety and effectiveness of the subject device.

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
- 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 Verification

1) 2D Vessel Analysis
The user manually sets anchor points on a stenotic region of blood vessels to extract the vessel contour, stenosis scope and position, and the following parameters are calculated: Vessel Diameter, Vessel Length, Stenosis Diameter, Stenosis Length, Stenosis Rate.

a) Test Mothed
   - Evaluation by Angiography Phantom
   - Comparing with the ground truth established by the experts in clinical cases.

b) Data Description
- 2D XA image of vessel stenosis standard phantom
- 30 clinical cases include15 cases 2D coronary angiography images, 10 cases 2D cerebral artery digital subtraction angiography images and 5 cases 2D lower limb artery digital subtraction angiography images.

c) Results

Parameters	Mean Relative Error Rate (MRE %)
Dstenosis	2.11 % (95% CI: 1.57-2.61%)
Dmax	1.71 % (95% CI:1.20-2.30%)
Dmin	1.93 % (95% CI:1.30-2.60%)
Ref D1	1.20 % (95% CI:0.80-1.60%)
Ref D2	1.14 % (95% CI:0.70-1.50%)
Interpolated D	1.14 % (95% CI:0.70-1.60%)
Stenosis Length	0.49 % (95% CI: 0.26-0.79%)
Stenosis Rate	Bland-Altman analysis: 96.33% of points within limits of agreement (LoA: -3.35% to +3.19%)

Notes: The Vessel Length is defined as the Stenosis Length when the user manually adjusts Ref 1 and Ref 2 to the head and tail endpoints of the blood vessel segment. Since its underlying algorithm is identical to the independently validated algorithm for Stenosis Length, this output is also considered verified.

2) Left Ventricular Analysis

Based on 2D DSA fluoroscopic images, end-diastolic volume (EDV), end-systolic volume (ESV), ejection fraction (EF), and stroke volume (SV) are calculated from physician-delineated contours of the left ventricle. Using the same contour data, wall motion analysis is performed, which computes the displacement of 100 equidistant points along the ventricular wall and generates a standardized displacement map.

a) Test Mothed
- EDV, ESV, SV and EF were evaluated based on a comparison with the Ground Truth derived from the CAMUS dataset.
- Wall motion analysis was evaluated based on the rationality of each algorithmic step. The output (standardized displacement map) is generated by normalizing the displacement of 100 equidistant points along the centerline against the perimeter of the ventricular wall contour at end-diastole (ED). The contour was manually delineated by a clinician to ensure its rationality. And the rationality of point displacement was assessed according to the centering degree of the centerline and the orthogonality of displacement vectors.

b) Data Description
- For EDV, ESV, SV and EF evaluation, 60 left ventricular binarized images with ground truth for ventricular volume and ejection fraction derived from the CAMUS dataset, and includes 18 cases of heart failure with reduced EF (HfrEF), 14 cases of mildly reduced EF (HfmrEF), and 28 cases of preserved EF (HfpEF).
- For Wall Motion Analysis evaluation, 30 left ventricular binarized images

derived from the CAMUS dataset, and includes 11 cases of heart failure with reduced EF (HfrEF), 8 cases of mildly reduced EF (HfmrEF), and 11 cases of preserved EF (HfpEF).

c) Results

■ EDV, ESV, SV and EF

Parameter	Result
EDV (SR method)	Bland-Altman analysis: 100% of points within limits of agreement (LoA: -9.61 to +11.5 mL)
EDV (AL method)	Bland-Altman analysis: 100% of points within limits of agreement (LoA: -12.45 to +8.65 mL)
ESV (SR method)	Bland-Altman analysis: 100% of points within limits of agreement (LoA: -5.61 to +3.80 mL)
ESV (AL method)	Bland-Altman analysis: 95.5% of points within limits of agreement (LoA: -7.84 to +4.19 mL)
SV (SR method)	Bland-Altman analysis: 95.5% of points within limits of agreement (LoA: -6.44 to 10.12 mL)
SV (AL method)	Bland-Altman analysis: 95.5% of points within limits of agreement (LoA: -8.03 to 7.89 mL)
EF (SR method)	Bland-Altman analysis: 95.5% of points within limits of agreement (LoA: -3.02 to +4.68 mL)
EF (AL method)	Bland-Altman analysis: 100% of points within limits of agreement (LoA: -3.02 to +4.68 mL)

■ Wall Motion Analysis

Centerline Rationality: The centerline is required to be equidistant from the ED and ES contours. Tests confirmed that the upper limit of the 95% CI for the mean absolute difference (MAD) between the centerline and both contours was less than 1 pixel. The accuracy achieves sub-pixel level, meeting the centering geometric requirement.

Displacement Vector Orthogonality: The motion of ventricular wall points must be perpendicular to the centerline. Statistical analysis confirmed no significant deviation from 90° in the displacement direction relative to the centerline tangent (all p-values > 0.05), strongly supporting orthogonality.

Notes: Left Ventricular analysis is not intended to replace echocardiography. The clinical ground truth for left ventricular wall motion analysis is echocardiography. This device, designed as a purely manual assistive tool, aims to improve clinicians' efficiency in identifying left ventricular wall motion abnormalities and is not a substitute for echocardiography or other clinical diagnostic methods. It is important to note that due to various constraints (such as the imaging quality of left ventricular angiography, the selection of ED/ES phases, and the accuracy of physician-delineated contours), the quantitative outputs of the device are not directly applicable for clinical decision-making related to cardiac disease/abnormalities.

3) 2D Blood Flow Analysis

Using 2D digital subtraction angiography data to calculate parameters, including Arrival Time (AT), Time to Peak (TTP), Wash-in Rate (WIR), Width, Area Under Curve (AUC), Mean Transit Time (MTT) and Rise Time (RT).

a) Test Mothed

- To validate the Time to Peak (TTP) measurement, 200 time-intensity curves (TICs) from clinical DSA images were analyzed. Ground truth TTP was manually annotated from the TIC based on definition. Agreement between computed and manual TTP was evaluated using intraclass correlation coefficient (ICC) and Bland–Altman analysis.
- The simulation study expanded verification to all algorithm parameters (AT, TTP, WIR, Width, AUC, MTT and RT). This phase used 1000 simulated TICs designed to mimic real-world blood flow dynamics, verified through maximum mean discrepancy (MMD) test (p=0.9997). The ground truth was the simulation parameters. The consistency was evaluated via ICC, Bland–Altman analysis.

b) Data Description

- **Verification of TTP:** 20 DSA images of 13 cases, including 10 sets of head images and 10 sets of lower limb images. We sampled 10 points within the vascular regions of each image, and finally obtained 200 TIC samples for verification.
- **Simulation study for all algorithm parameters:** Simulated time-intensity curves (TICs) were generated by combining theoretical contrast dynamics models with statistical features extracted from real clinical DSA data covering diverse vascular pathologies, including stenosis, aneurysms, and infarctions, etc. The simulation produced 1,000 TICs incorporating physiological and pathological hemodynamic variations. These generated TICs demonstrated statistical equivalence to real clinical data (MMD test, p=0.999), providing validated benchmarks for algorithm testing.

c) Results

- **Verification of TTP：** The results demonstrated excellent agreement, with an ICC of 0.9983 and 97% of data points falling within the limits of agreement (LoA) in B-A plot. The LoA was -0.2755 to 0.2191, the mean absolute error (MAE) with 95% confidence interval (CI) was 0.1071 (0.0971 - 0.1169), and the mean relative error (MRE) with 95% CI was 2.5458% (2.2535% - 2.8573%).

- **Simulation study for all algorithm parameters:** All parameters achieved ICC values exceeding 0.998, with 95% - 98% of points falling within the LoA of B-A plots, which showed excellent agreement between the algorithm results and ground truth. The result of Wilcoxon signed-rank tests confirmed non-significant differences (p>0.05) between them. The various statistical indicators are listed in the table below, including the results of ICC, B-A analysis, p-value of Wilcoxon signed-rank test, MAE and MRE with 95% CI

for all the parameters.

Parameter	ICC	Point within LoA	LoA	P-value	MAE % (95% CI)	MRE% (95% CI)
AT	0.9996	96.6%	-0.494 - 0.052	0.4290	0.005 (0.004-0.007)	0.178 (0.126-0.235)
TTP	0.9995	98.1%	-0.090 – 0.093	0.3850	0.024 (0.022-0.027)	0.444 (0.397-0.492)
WIR	0.9995	95.1%	-32.980 – 34.129	0.9227	7.972 (7.072-8.938)	1.737 (1.612-1.864)
Width	0.9992	98.1%	-0.0922 – 0.0961	0.4347	0.025 (0.022-0.027)	0.683 (0.610-0.760)
AUC	0.9999	95.1%	- 51.786 – 50.280	0.4573	20.973 (20.043-21.922)	0.949 (0.900-0.999)
MTT	0.9992	95.2%	-0.095 – 0.0950	0.7254	0.030 (0.027-0.032)	1.090 (1.002-1.179)
RT	0.9988	96.1%	-0.105 – 0.106	0.4062	0.028 (0.026-0.031)	1.149 (1.024-1.276)

4) Stitching

Stitching combines several small images with overlapping areas into a single image for visualization purposes.

a) Test Mothed

- Validate the result of image registration by evaluating the mean target registration error (mTRE);
- Validate Stitching results through the clinical specialist assessments.

b) Data Description

- For validation the result of image registration, six 2D-DSA images were used, including arterial and venous acquisitions. Select ten key points from critical anatomical areas in each image to calculate the mean target error, totaling 60 points.
- For validation of the result of image stitching, twenty 2D-DSA images were used for the verification of the stitching result, including arterial and venous acquisitions.

c) Results

- **Image registration accuracy testing**. All mTRE values (ranging 0.004-0.037mm) were significantly lower than the pixel diagonal distance (ranging 0.360-0.455mm across images);
- Clinical quality assessment by two U.S.-certified physicians. All stitched clinical cases received perfect scores of 3 on the 3-point scale, indicating no visible seams or structural discontinuities in vascular, bone, or tissue structures;

Notes: The purpose of the stitched image is only for visualization purposes, and not intended for navigation or diagnosis.

Other Standards and Guidance

- 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).

- Cybersecurity in Medical Devices Quality System Considerations and Content of Premarket Submissions.
- Content of Premarket Submissions for Device Software Functions.

Summary

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

9. Substantially Equivalent (SE) Conclusion

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

In summary, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device and reference device.