September 24, 2025

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

Re: K250045
Trade/Device Name: uWS-Angio Pro
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 25, 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)*
K250045

Device Name
uWS-Angio Pro

Indications for Use *(Describe)*
The uWS-Angio Pro is a post-processing software based on the uWS-Angio Basic for viewing, processing, evaluating and analyzing CT, MR, 3D XA images, and overlaying 2D medical images to support image guidance during interventional procedures. It has the following application:
The uWS-Angio Pro uTarget view application is intended to provide tools for adding the trajectory to the lesion. It also supports overlay of 3D datasets on 2D fluoroscopy images.
The uWS-Angio Pro uEmbo View application is intended to provide users with tools for planning and guiding interventional procedures. It offers a suite of features to mark targets, detect feeder vessels, and overlay the 3D image with the feeders and the corresponding anatomical X-ray image. When the overlay function is activated, it supports automatic 2D-3D image registration specifically for head neuroimaging, while the manual registration function is not restricted to any specific anatomical region.
The uWS-Angio Pro uCardiac View application is intended to provide users tools to plan and guide the interventional procedures. This application can use CT angiography images for vascular access analysis, aortic root analysis and angle management, and overlay registration display with 2D XA images.

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 24, 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 Pro
Common Name: Angiography X-ray Image Processing Software
Model(s): uWS-Angio Pro

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

Reference Device#1
510(k) Number: K142273
Device Name: EmboGuide

Reference Device#2
510(k) Number: K233209
Device Name: uOmnispace.CT

5. Device Description

uWS-Angio Pro is a 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 Pro contains the following applications:
- uWS-Angio Pro uTarget View
- uWS-Angio Pro uEmbo View
- uWS-Angio Pro uCardiac View

6. Indications for use

The uWS-Angio Pro is a post-processing software based on the uWS-Angio Basic for viewing, processing, evaluating and analyzing CT, MR, 3D XA images, and overlaying 2D medical images to support image guidance during interventional procedures. It has the following application:

The uWS-Angio Pro uTarget view application is intended to provide tools for adding the trajectory to the lesion. It also supports overlay of 3D datasets on 2D fluoroscopy images.

The uWS-Angio Pro uEmbo View application is intended to provide users with tools for planning and guiding interventional procedures. It offers a suite of features to mark targets, detect feeder vessels, and overlay the 3D image with the feeders and the corresponding anatomical X-ray image. When the overlay function is activated, it supports automatic 2D-3D image registration specifically for head neuroimaging, while the manual registration function is not restricted to any specific anatomical region.

The uWS-Angio Pro uCardiac View application is intended to provide users tools to plan and guide the interventional procedures. This application can use CT angiography images for vascular access analysis, aortic root analysis and angle management, and overlay registration display with 2D XA images.

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 Pro	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 Pro and the predicate device syngo Application Software share similar indications for use: providing image viewing and processing to support device guidance during interventional procedures. 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 proposed 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 Pro applications

Application	Function name	Proposed device uWS-Angio Pro	Predicate device syngo Application Software	Reference device#1 EmboGuide (K142273)	Reference device#2 uOmnispace.CT (K233209)	Remark

			(K230955)			
uTarget View	Trajectory planning	Yes	Yes	/	/	Note 1
	Overlay	Yes	Yes	/	/	Same
	Sending position data	Yes	Yes	/	/	Note 2
uEmbo View	Feeder Detection	Yes	/	Yes	/	Same
	Overlay	Yes	/	Yes	/	Same
uCardiac View	Vascular Access Analysis	Yes	/	/	Yes	Note 3
	Aortic Root Analysis	Yes	/	/	Yes	Note 4
	Overlay	Yes	Yes	/	/	Same
	Sending angle	Yes	Yes	/	/	Note 2

Note 1: Compared to the predicate device, uTarget view application is intended to provide tools for adding lesion markers (bounding box) and the trajectory to the lesion. The difference doesn't impact the safety and effectiveness of the subject device.

Note 2: Compared to the predicate device, position data of the proposed device are compatible to the Angiography Systems of United-Imaging Healthcare. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the device.

Note 3: Compared to the reference device#2, the name of the function is different. The Vascular Access Analysis is the same as the Vessel analysis function of Cardiovascular Combined Analysis application in the reference device#2. The difference doesn't impact the safety and effectiveness of the subject device.

Note 4: Compared to the reference device#2, the Aortic Root Analysis is the same as the combination of TAVI evaluation function and Heart analysis function of Cardiovascular Combined Analysis application in the reference device#2. 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 (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 Verification

(1) uTarget View

- **Workflow Test**

a) Device Output

- Trajectory
- entry position data and lateral position data
- overlay planned trajectory with 3D image and 2D XA image

b) Test Data Description

- XA CBCT series and CT\MR data of the same patient

c) c) Test Method

- System Test

d) Results

- The uTarget View generated a trajectory line that is displayed on both the MPR and VR images and added to the trajectory list.
- Sent entry position data and lateral position data to the United Imaging Healthcare Angiography system.
- The uTarget View planned trajectory with 3D image and 2D XA image.

(2) uEmbo View

➢ **Path Generation Algorithm**

Based on XA 3D abdominal data or XA 3D head data, the paths to the target points from the catheter port are calculated based on user-marked locations.

e) Device Output

- Three-dimensional path to the target points from the catheter port, and it does not involve outputting quantitative parameters.

f) Test Data Description

- 40 cases of XA 3D data, including 62 hepatic artery branches from 23 patients and 50 intracranial artery branches from 17 patients.

g) Test Method

The path generation result was validated through a subjective evaluation conducted by U.S.-certified physicians.

h) Results

To verify the method's effectiveness, we evaluated it on 112 vascular paths from 40 clinical cases. Independent physicians reviewed the results and confirmed that all paths were successfully generated without any critical clinical errors, such as vessel wall penetration or incorrect branching. All paths received final clinical approval.

➢ **Neuro Registration Algorithm**

Based on 2D XA images and 3D XA images, perform 2D-3D registration for data in neural scenes.

a) Device Output

The result of 2D-3D registration, and it does not involve outputting quantitative parameters.

b) Test Data Description

The test dataset consisted of 37 real clinical cases of head XA data.The dataset was clinically diverse, including patients of varying ages, genders, and disease types (e.g., arterial stenosis, cerebral infarction), and encompassed challenging scenarios such as brain anatomy shift.

c) Test Method

The accuracy of the registration was evaluated using the mTRE between corresponding points in key anatomical regions, pre- and post-registration.

d) Results

All 37 cases across all predefined transformations passed the verification criterion. The overall mean mTRE was 0.24 mm (95% CI: 0.21 to 0.28 mm), significantly below the 1 mm;
The average registration time was 1.75 s (95% CI: 1.69 to 1.82 s).

(3) uCardiac View

➢ **Aortic Root Vessel Extraction**

Based on the 3D CTA images, we use deterministic algorithm to segment the aortic root.

a) Device Output

Segmentation results

- Aorta
- Left Ventricle
- Left coronary artery
- Right coronary artery

b) Test Data Description

- A total of 39 CTA datasets were included, comprising 25 patients from the USA and 14 from China. Among these patients, 25 presented with calcification.

c) Test Method

- Evaluation with the ground truth, with evaluation conducted using the DICE coefficient.

d) Results

Volume Targets	Aorta	Left Ventricle	Left Coronary Artery	Right Coronary Artery
DICE(Algorithm result)	0.987 (95% CI 0.9862–0.9878)	0.981 (95% CI 0.9786–0.9834)	0.911 (95% CI 0.9047–0.9173)	0.908 (95% CI 0.9002-0.9158)

➢ **Aortic Vessel Extraction Algorithm**

Based on the 3D CTA images, we use deterministic algorithm to segment the aorta.

a) Device Output

Segmentation results

- Aorta

b) Test Data Description

- A total of 39 CTA datasets were included, comprising 13 patients from the USA and 26 from China. The patient cohort included 10 cases with calcification, 7 with aneurysm, 4 with aortic dissection, and 7 with hematoma.

c) Test Method

- Evaluation with the ground truth, with evaluation conducted using the DICE coefficient.

d) Results

- The DICE value is 0.968(95% CI 0.9652-0.9708).

➢ **Parameter Calculation**

Based on the 3D CTA images and the preceding image processing, we use simple geometry principle to calculate the parameters, including area, diameter, distance, perimeter and length.

a) Device Output and Quantitative Parameters

- Area
- Diameter
- Perimeter

b) Test Data Description

- **Aortic Root Parameter Calculation:** A total of 39 CTA datasets were included, comprising 25 patients from the USA and 14 from China. Among these patients, 25 presented with calcification.
- **Aortic Vessel Parameter Calculation:** A total of 39 CTA datasets were included, comprising 13 patients from the USA and 26 from China. The patient cohort included 10 cases with calcification, 7 with aneurysm, 4 with aortic dissection, and 7 with hematoma.

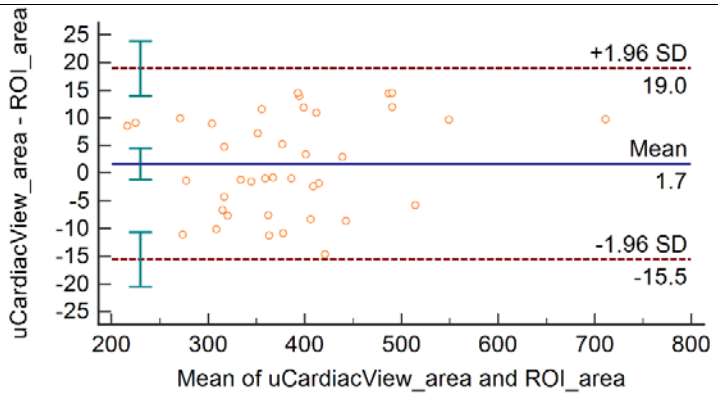
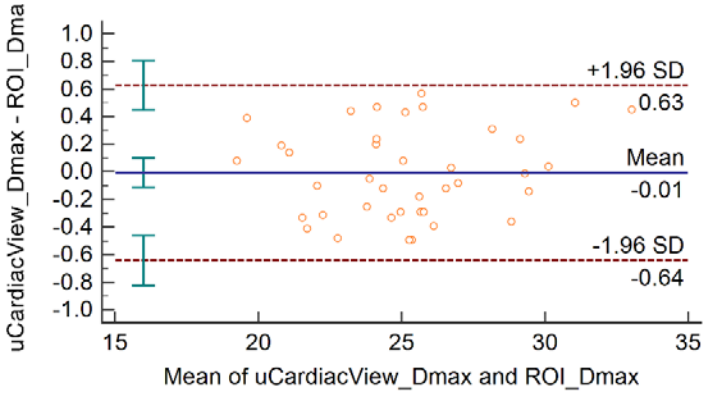
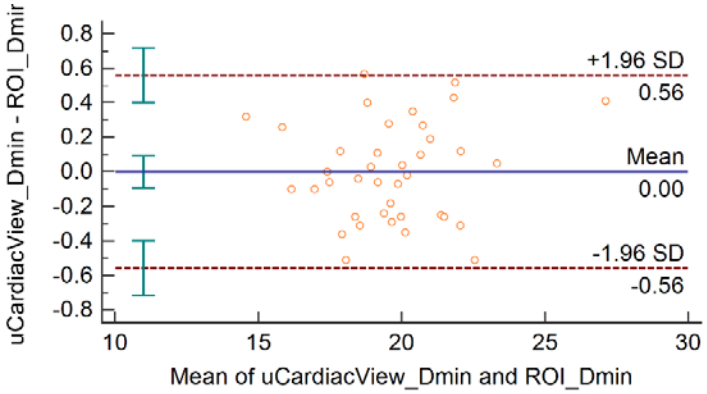
c) Test Method

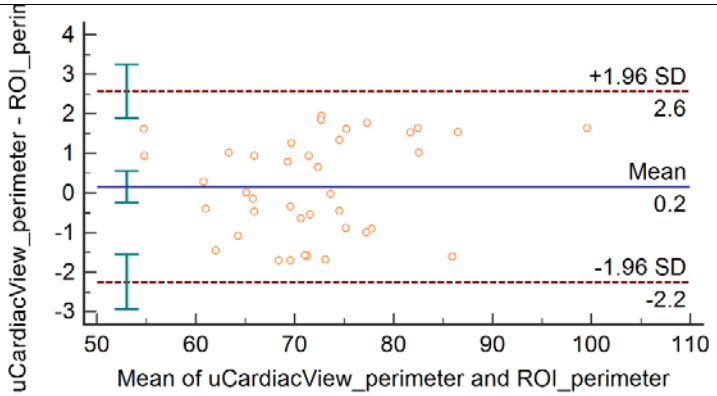
- Evaluation with the ground truth, with evaluation conducted using the intraclass correlation coefficient (ICC) and Bland Altman plots.

d) Results

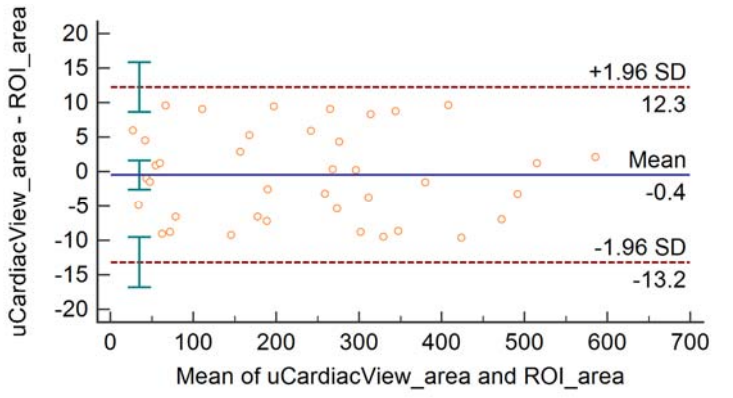
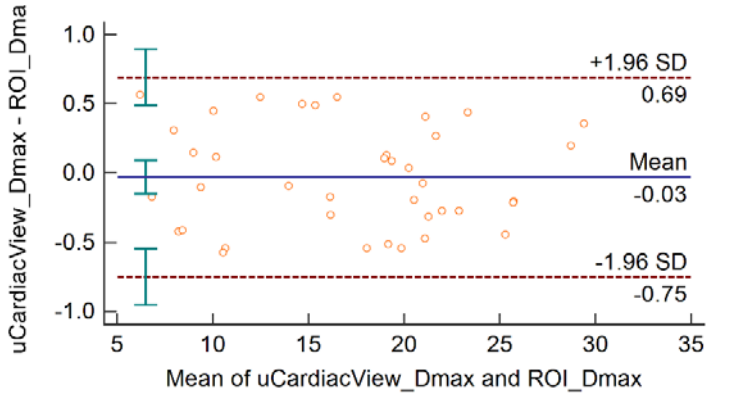
- **Aortic Root Parameter Calculation:**

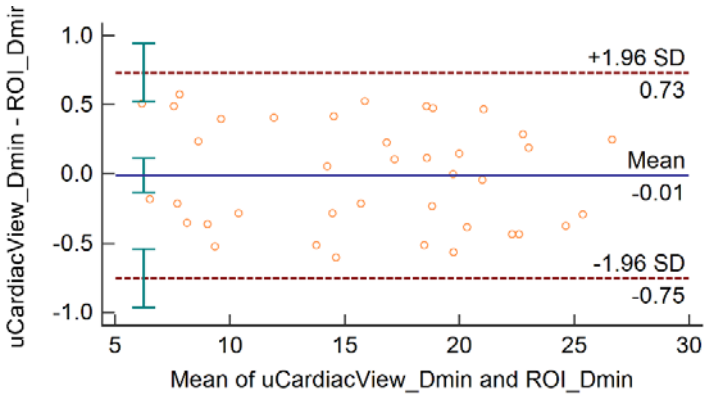
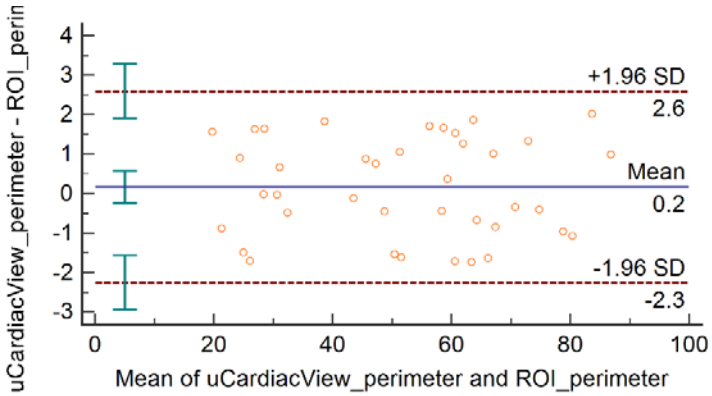
Parameters	Analysis Results (including ICC and BA-plot)
Area	ICC: 0.9995 (95% CI: 0.9994 to 0.9995) Bland-Altman analysis: 100% of points within limits of agreement (LoA: -15.5 to +19.0 mm^2)

	
Maximum diameter	0.9985 (95% CI: 0.9980 to 0.9989) Bland-Altman analysis: 100% of points within limits of agreement (LoA: -0.64 to +0.63 mm) 
Minimum diameter	0.9992 (95% CI: 0.9989 to 0.9994) Bland-Altman analysis: 97.4% of points within limits of agreement (LoA: -0.56 to +0.56 mm) 
Perimeter	0.9957 (95% CI: 0.9952 to 0.9960) Bland-Altman analysis: 100% of points within limits of agreement (LoA: -2.2 to +2.6 mm)

■ Aortic Vessel Parameter Calculation:

Parameter	ICC results & Bland-Altman Analysis
Area	0.9991 (95% CI: 0.9988 to 0.9993) Bland-Altman analysis: 100% of points within limits of agreement (LoA: -13.2 to +12.3 mm^2) 
Maximum diameter	0.9983 (95% CI: 0.9969 to 0.9991) Bland-Altman analysis: 100% of points within limits of agreement (LoA: -0.75 to +0.69 mm) 

Minimum diameter	0.9979 (95% CI: 0.9960 to 0.9989) Bland-Altman analysis: 100% of points within limits of agreement (LoA: -0.75 to +0.73 mm) 
Perimeter	0.9980 (95% CI: 0.9961 to 0.9989) Bland-Altman analysis: 100% of points within limits of agreement (LoA: -2.3 to +2.6 mm) 

Note: features driven by user-input and the features permitting user editing as follow:

- **Features driven by user input**

Application	Algorithm	Feature	User input
uTargetView	N.A.	Path Planning	Adding the entry spot and the target spot
	N.A.	Bounding Box ROI Placement	Holding down and dragging the mouse on the lesion to draw the long axis.
uEmboView	Path Generation	Feeder Detection	The user needs to mark the target points and catheter port

- **Features permitting user editing**

Application	Algorithm	Editing Content
uEmboView	Path Generation	Path Results
	Neuro Registration	Registration Results
uCardiacView	Aortic Root Vessel Extraction	Segmentation Results
	Aortic Root Parameter Calculation	Vascular Contour
	Aortic Vessel Extraction	Segmentation Results
	Aortic Vessel Parameter Calculation	Vascular Contour

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 Pro 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.