September 6, 2024

Shanghai United Imaging Intelligence Co., Ltd.
Xiaojing Zhao
Quality & Regulatory Manager
No. 701 Yunjin Road, Xuhui District
Shanghai, 200232
China

Re: K240411
Trade/Device Name: uAI Portal
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: August 14, 2024
Received: August 15, 2024

Dear Xiaojing Zhao:

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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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.

Submission Number *(if known)*

K240411

Device Name

uAI Portal

Indications for Use *(Describe)*

uAI Portal is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications:
The Lower Extremity Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating CTA images of lower extremities.
The Head and Neck Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with head and neck CTA.
The Coronary Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with CCTA.
The Pulmonary Artery Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with CTPA.
The Aorta Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with aorta CTA.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

United Imaging Intelligence 联影智能

510 (k) SUMMARY

1. Date of Preparation:

February 8, 2024

2. Sponsor Identification

Shanghai United Imaging Intelligence Co., Ltd.

No. 701 Yunjin Road, Xuhui District, Shanghai, 200232, PEOPLE'S REPUBLIC OF CHINA

Contact Person: Xiaojing Zhao

Position: Regulatory Specialist

Tel: +86-021-67076888-5386

Email: xiaojing.zhao@uii-ai.com

Primary Contact Correspondent: MCRA Digital Health

Contact Person: Nima Akhlaghi

Position: Director, Digital Health, AI & Imaging Center Lead

Tel: 202-742-3889

Email: nakhlaghi@mcra.com

3. Identification of Proposed Device

Trade Name: uAI Portal

Common Name: Medical image management and processing system

Model(s): uAI Portal

Regulatory Information

Classification Name: Medical image management and processing system

Classification: II

Product Code: QIH, LLZ

Regulation Number: 21 CFR 892.2050

Review Panel: Radiology

4. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K183170
Device Name: uWS-CT

5. Device Description

uAI Portal is a comprehensive software solution designed to process, review and analyze CT studies. It can transfer images in DICOM 3.0 format over a medical imaging network or local file system. These images can be functional data, as well as anatomical datasets. It can be at one or more time-points or include one or more time-frames. Multiple display formats including VR, MIP, MPR, Probe, CPR, and SCPR. A trained, licensed physician can interpret these displayed images as well as the statistics as per standard practice.

uAI Portal contains the following applications:

- The Lower Extremity Vessel Analysis
- The Head and Neck Vessel Analysis
- The Coronary Analysis
- The Pulmonary Artery Analysis
- The Aorta Analysis

6. Indications for use

uAI Portal is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications:

- The Lower Extremity Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating CTA images of lower extremities.
- The Head and Neck Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with head and neck CTA.
- The Coronary Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with CCTA.
- The Pulmonary Artery Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with CTPA.
- The Aorta Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with aorta CTA.

7. Summary of Technological Characteristics

uAI Portal offers a fast and user-friendly solution for reconstructing medical images by utilizing automatic segmentation results generated by artificial intelligence algorithms.

The system parses DICOM images, extracts some tags and then fill the information to database. Datachecking is performed based on the information to verify whether the data can be processed by any of the application. Then the algorithms will be called to process the images in memory and output the segmented results. The segmented results will be stored in hard drive. The system uses database to retrieve the information and record some operation status.

Once users select any data and choose one application, the application will start and load the images files to memory. The original images and the processing results can be displayed in the software interface. Various types of views depending on the selected application are displayed by respective algorithms in the software interface. Basic operations like zooming, panning, adjusting window, and measurements can be performed on the displayed images. Users have the options to save images or results to PACS for storage or send them to Filming for printing. Additionally, user configuration is provided, allowing users to customize their settings in each application.

Both the proposed and predicate device have the similar general information, such as Device Classification Name, Product Code, Classification Panel, Intended Use described in Table 1.
The proposed and predicate device also have the same advanced applications in following:

- Lower Extremity Vessel Analysis
- Head and Neck Vessel Analysis
- Coronary Analysis
- Pulmonary Artery Analysis
- Aorta Analysis

The differences between the proposed and the predicate device are listed as follows:

- The CT Vessel Analysis application of the predicate device includes the Aorta Analysis application, Head and Neck Vessel Analysis application, Lower Extremity Vessel Analysis application and Pulmonary Artery Analysis

application of the proposed device; The CT Heart application of the predicate device offer similar functions as Coronary Analysis application of the proposed device.

- The CT Vessel Analysis application of the predicate device provides combined segmentation results of vessels and inseparable parts of organs, whereas the proposed device provides segmentation results of vessels in the Aorta Analysis application and Pulmonary Artery Analysis application.

Table 1 Comparison of general information

Item	**Proposed Device** **uAI Portal**	**Predicate Device** **uWS-CT(K183170)**	**Remark**
Device Classification Name	Medical image management and processing system	Picture Archiving and Communications System	The FDA has changed its regulatory classification of PACS (Picture Archiving and Communication Systems), referring to it now as MIMPS (medical image management and processing systems) as part of amended regulatory classification changes made for radiology-specific software.
Product Code	QIH, LLZ	LLZ	Both LLZ and QIH are product code of Medical image management and

Item	Proposed Device uAI Portal	Predicate Device uWS-CT(K183170)	Remark
			processing system, the difference between them is use different algorithms.
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	The predicated device includes more applications, which is discussed in the following sections, than the proposed device. This difference will not impact the safety and effectiveness of the

Item	Proposed Device uAI Portal	Predicate Device uWS-CT(K183170)	Remark
			device.
Intended Use	uAI Portal is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: ● The Lower Extremity Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating CTA images of lower extremities. ● The Head and Neck Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with head and neck CTA.	uWS-CT is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: ● The CT Oncology application is intended to support fast-tracking routine diagnostic oncology, staging, and follow-up, by providing a tool for the user to perform the segmentation and volumetric evaluation of suspicious lesions in lung or liver. ● The CT Colon Analysis application is intended to provide the user a tool to	The intended use is decreased. The predicated device includes more applications, which is discussed in the following sections, than the proposed device. This difference will not impact the safety and effectiveness of the device.

Item	Proposed Device uAI Portal	Predicate Device uWS-CT(K183170)	Remark
	● The Coronary Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with CCTA. ● The Pulmonary Artery Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with CTPA. ● The Aorta Analysis is intended to provide a tool for viewing, manipulating, and evaluating imaging datasets acquired with aorta CTA.	enable easy visualization and efficient evaluation of CT volume data sets of the colon. ● The CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw. ● The CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. ● The CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images. The Inner view application is intended to perform a	

Item	Proposed Device uAI Portal	Predicate Device uWS-CT(K183170)	Remark
		virtual camera view through hollow structures (cavities), such as vessels. ● The CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure information to evaluate the lung and airway. ● The CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in the brain. The CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function.	

Item	Proposed Device uAI Portal	Predicate Device uWS-CT(K183170)	Remark
		● The CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score. The CT Dynamic Analysis application is intended to provide visualization of the CT datasets over time with the 3D/4D display modes. ● The CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk. ● The CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction. It also provides a tool for the user to perform liver separation and residual liver segments evaluation.	

Table 2 SE Discussion for different Advanced Applications

Application	**Function name**	**Proposed device** uAI Portal Lower Extremity Vessel Analysis	**Predicate device** uWS-CT(K183170) CT Vessel Analysis	**Remark**
Lower Extremity Vessel Analysis	Image Browsing	Yes	Yes	Same
	Image Editing	Yes	Yes	Same
	Vessel Segmentation	Yes	Yes	Same
	Bone Segmentation	Yes	Yes	Same
	Centerline Extraction	Yes	Yes	Same
	ROI	Yes	Yes	Same
	Measurement	Yes	Yes	Same
	Stenosis Measurement	Yes	Yes	Same

Application	Function name	Proposed device uAI Portal Lower Extremity Vessel Analysis	Predicate device uWS-CT(K183170) CT Vessel Analysis	Remark
	Print	Yes	Yes	Same
	Archive	Yes	Yes	Same
	User Configuration	Yes	Yes	Same

Application	Function name	Proposed device uAI Portal Head and Neck Vessel Analysis	Predicate device uWS-CT(K183170) CT Vessel Analysis	Remark
Head and Neck Vessel Analysis	Image Browsing	Yes	Yes	Same
	Image Editing	Yes	Yes	Same

Application	Function name	Proposed device uAI Portal Head and Neck Vessel Analysis	Predicate device uWS-CT(K183170) CT Vessel Analysis	Remark
	Vessel Segmentation	Yes	Yes	Same
	Bone Segmentation	Yes	Yes	Same
	Centerline Extraction	Yes	Yes	Same
	Measurement	Yes	Yes	Same
	Print	Yes	Yes	Same
	Archive	Yes	Yes	Same
	User Configuration	Yes	Yes	Same

Application	**Function name**	**Proposed device** uAI Portal Coronary Analysis	**Predicate device** uWS-CT(K183170) CT Heart	**Remark**
Coronary Analysis	Image Browsing	Yes	Yes	Same
	Image Editing	Yes	Yes	Same
	Heart Segmentation	Yes	Yes	Same
	Vessel Segmentation	Yes	Yes	Same
	Centerline Extraction	Yes	Yes	Same
	Measurement	Yes	Yes	Same
	Stenosis Measurement	Yes	Yes	Same

Application	**Function name**	**Proposed device** uAI Portal Coronary Analysis	**Predicate device** uWS-CT(K183170) CT Heart	**Remark**
	Print	Yes	Yes	Same
	Archive	Yes	Yes	Same
	User Configuration	Yes	Yes	Same

Application	**Function name**	**Proposed device** **uAI Portal** **Pulmonary Artery Analysis**	**Predicate device** **uWS-CT(K183170)** **CT Vessel Analysis**	**Remark**
Pulmonary Artery Analysis	Image Browsing	Yes	Yes	Same
	Image Editing	Yes	Yes	Same
	Segmentation	Yes	Yes	The CT Vessel Analysis Application of

Application	Function name	Proposed device uAI Portal Pulmonary Artery Analysis	Predicate device uWS-CT(K183170) CT Vessel Analysis	Remark
				uWS-CT (K183170) provide vessel segmentation results with organs. The uAI Portal Pulmonary Artery Analysis offer segmentation results of vessels. For the evaluation of vessel, the difference in segmentation between the predicate device and proposed device will not impact the safety and effectiveness of the device
	Measurement	Yes	Yes	Same
	Print	Yes	Yes	Same
	Archive	Yes	Yes	Same
	User Configuration	Yes	Yes	Same

Application	Function name	Proposed device uAI Portal Aorta Analysis	Predicate device uWS-CT(K183170) CT Vessel Analysis	Remark
Aorta Analysis	Image Browsing	Yes	Yes	Same
	Segmentation	Yes	Yes	Organ segmentation results have slight difference due to the different applied algorithm of the predicate device and proposed device. For the evaluation of vessel, those other segmentation difference between the predicate device and proposed device will not impact the safety and effectiveness of the device
	Centerline Extraction	Yes	Yes	Same
	Measurement	Yes	Yes	Same
	Lumen Diameter	Yes	Yes	Same

Application	Function name	Proposed device uAI Portal Aorta Analysis	Predicate device uWS-CT(K183170) CT Vessel Analysis	Remark
	Measurement			
	Print	Yes	Yes	Same
	Archive	Yes	Yes	Same
	User Configuration	Yes	Yes	Same

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 Verification and Validation
Software verification and validation testing was provided to demonstrate safety and efficacy of the proposed device.

Per FDA Guidance "GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES", dated June 14, 2023, the Level of Concern of the software contained in the proposed device is determined to be: Basic Documentation Level.

Those documentations include:

- Software Description
- Risk Management File
- Software Requirements Specification (SRS)
- Software Architecture Diagram
- Software Development Environment Description
- Software Verification and Validation
- Software Version History
- Cybersecurity Documents

Animal Study
No animal study was required.

Clinical Studies
No clinical study was required.

Performance Verification
Algorithm training of uAI Portal software has been conducted on images collected from China as training dataset. The data set ensures a variety of data for the different

gender, age, equipment and CT protocol. Algorithm verification has been conducted on US images.

To validate the uAI Portal software from a clinical perspective, the AI-based segmentation Algorithm contained in the product underwent a scientific evaluation. The results of clinical data-based software validation for the proposed device demonstrated high consistency in comparison to the predicate device.

Regarding the validation of the algorithm, the test data was used independently from training dataset.

The algorithm testing of uAI Portal has been performed using 150 images collected from US, which covered different gender, age, ethnicity, equipment and CT protocol used to collect images. The information of demographic and equipment distribution was as follows:

Demographic information		**Quantity/Years**
Gender	Female	73
	Male	77
Age	Median	66Y
	Min	19Y
	Max	91Y
Equipment	SIEMENS	55
	GE	85
	TOSHIBA	10
Artifacts	With artifacts	33
	Without artifacts	117
Anatomical variation	With anatomical variation	30
	Without anatomical variation	120

Acceptance Criteria

In order to verify the effectiveness of the algorithm in the proposed device, we compared the segmentation results with the ground truth. The validation type and acceptance criteria is shown below:

Validation Type	**Application**	**Algorithm**	**Acceptance Criteria**
Dice, DICE is defined as follows: $DICE = \frac{2\|G \cap P\|}{\|G\| + \|P\|}$, where G is	Coronary Artery	Vessels segmentation	0.85
		Heart segmentation	0.90
	Head and Neck Vessel	Head vessel segmentation	0.85
		Neck vessel	0.90

the ground truth, and P is the segmentation result.		segmentation	
	Aorta	Trunk segmentation	0.90
		Branches segmentation	0.80
	Pulmonary Artery	Arteries segmentation	0.85
		Veins segmentation	0.85
	Lower Extremity Artery	Arteries segmentation	0.80

During the ground truthing process, two Chinese radiologists, each with at least 5 years of clinical experience, independently annotated vessel mask for each patient case, resulting in two sets of annotations per case. Both radiologists are hospital employees and are independent from United Imaging. After completion, an American Board-Certified Radiology adjudicator with at least 10 years of clinical experience reviewed both sets of segmented images. Based on his assessment, the adjudicator selected the most accurate segmentation set as the final ground truth. If needed, he would make any necessary modification until a satisfactory ground truth was established for the study.

The results output by algorithm were compared with the reference standard, the value of Dice coefficient were shown in the table below:

Application	**Algorithm**	**Average Dice**
Coronary Artery	Vessels segmentation	0.920
	Heart segmentation	0.980
Head and Neck Vessel	Head vessel segmentation	0.902
	Neck vessel segmentation	0.967
Aorta	Trunk segmentation	0.946
	Branches segmentation	0.846
Pulmonary Artery	Arteries segmentation	0.953
	Veins segmentation	0.933
Lower Extremity Artery	Arteries segmentation	0.892

The subgroups analysis was conducted based on gender, age, imaging equipment, anatomical variants, and imaging artifacts. The results were shown in the table below:

Coronary Artery Application

Algorithm	Gender	Average dice
Vessels segmentation	Female	0.912
	Male	0.924
	Age	Average dice
	＜40	0.915
	40~60	0.920
	＞60	0.923
	Manufacturer	Average dice
	GE	0.921
	SIEMENS	0.919
	Artifacts	Average dice
	With artifacts	0.929
	Without artifacts	0.919
	Anatomical variation	Average dice
	With anatomical variation	0.909
	Without anatomical variation	0.922
Heart segmentation	Gender	Average dice
	Female	0.983
	Male	0.978
	Age	Average dice
	＜40	0.987
	40~60	0.979
	＞60	0.979
	Manufacturer	Average dice
	GE	0.977
	SIEMENS	0.983
	Artifacts	Average dice
	With artifacts	0.983
	Without artifacts	0.979
	Anatomical variation	Average dice
	With anatomical variation	0.977
	Without anatomical variation	0.980

Head and Neck Vessel Application

Algorithm	Gender	Average dice
Head vessel segmentation	Female	0.902
	Male	0.902
	Age	Average dice
	＜40	0.905

	40~60	0.903
	＞60	0.901
	Manufacturer	Average dice
	GE	0.899
	SIEMENS	0.904
	TOSHIBA	0.910
	Artifacts	Average dice
	With artifacts	0.902
	Without artifacts	0.902
	Anatomical variation	Average dice
	With anatomical variation	0.899
	Without anatomical variation	0.905
Neck vessel segmentation	Gender	Average dice
	Female	0.966
	Male	0.968
	Age	Average dice
	＜40	0.959
	40~60	0.968
	＞60	0.968
	Manufacturer	Average dice
	GE	0.966
	SIEMENS	0.972
	TOSHIBA	0.967
	Artifacts	Average dice
	With artifacts	0.968
	Without artifacts	0.966
	Anatomical variation	Average dice
	With anatomical variation	0.968
	Without anatomical variation	0.966

Aorta Application

Algorithm	Gender	Average dice
Trunk segmentation	Female	0.941
	Male	0.950
	Age	Average dice
	＜40	0.949
	40~60	0.942
	＞60	0.947
	Manufacturer	Average dice
	GE	0.940

	SIEMENS	0.955
	TOSHIBA	0.948
	Artifacts	Average dice
	With artifacts	0.940
	Without artifacts	0.947
	Anatomical variation	Average dice
	With anatomical variation	0.949
	Without anatomical variation	0.945
Branches segmentation	Gender	Average dice
	Female	0.832
	Male	0.856
	Age	Average dice
	＜40	0.829
	40~60	0.837
	＞60	0.850
	Manufacturer	Average dice
	GE	0.853
	SIEMENS	0.830
	TOSHIBA	0.858
	Artifacts	Average dice
	With artifacts	0.822
	Without artifacts	0.850
	Anatomical variation	Average dice
	With anatomical variation	0.856
	Without anatomical variation	0.842

Pulmonary Artery Application

Algorithm	Gender	Average dice
Arteries segmentation	Female	0.955
	Male	0.951
	Age	Average dice
	＜40	0.946
	40~60	0.946
	＞60	0.957
	Manufacturer	Average dice
	GE	0.956
	SIEMENS	0.947
	Artifacts	Average dice
	With artifacts	0.960

	Without artifacts	0.953
	Anatomical variation	Average dice
	With anatomical variation	-
	Without anatomical variation	0.953
Veins segmentation	Gender	Average dice
	Female	0.936
	Male	0.930
	Age	Average dice
	＜40	0.944
	40~60	0.926
	＞60	0.936
	Manufacturer	Average dice
	GE	0.939
	SIEMENS	0.924
	Artifacts	Average dice
	With artifacts	0.931
	Without artifacts	0.933

Lower Extremity Artery Application

Algorithm	Gender	Average dice
Arteries segmentation	Female	0.880
	Male	0.910
	Age	Average dice
	40~60	0.881
	＞60	0.896
	Manufacturer	Average dice
	GE	0.878
	SIEMENS	0.907
	TOSHIBA	0.895
	Artifacts	Average dice
	With artifacts	0.906
	Without artifacts	0.890
	Anatomical variation	Average dice
	With anatomical variation	0.897
	Without anatomical variation	0.892

Other Standards and Guidance

- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set

- 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 2015-06 CONSOLIDATED VERSION).
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Document issued on September 27, 2023).

The features described in this premarket submission are supported with the results of the testing mentioned above; the uAI Portal was found to have a safety and effectiveness profile that is similar to the predicate device.

9. Substantially Equivalent (SE) Conclusion

The proposed device is equivalent to the predicate device with 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 devices.