Shanghai United Imaging Healthcare Co., Ltd
℅ Xin Gao
Regulatory Affairs Specialist
No. 2258 Chengbei Rd., Jiading Industrial District
Shanghai, Shanghai 201807
CHINA

June 1, 2020

Re: K192601
Trade/Device Name: uWS-MR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 29, 2020
Received: May 4, 2020

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192601

Device Name
uWS-MR

Indications for Use *(Describe)*
uWS-MR 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 MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages.
The Dynamic application is intended to provide a general post-processing tool for time course studies.
The Image Fusion application is intended to combine two different image series so that the displayed anatomical structures match in both series.
MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data.
The MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images.
The MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images.
The Brain Perfusion application is intended to allow the visualization of temporal variations in the dynamic susceptibility time series of MR datasets.
MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images.
The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels.
The DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images.
The United Neuro is intended to view, manipulate, and evaluate MR neurological images.
The MR Cardiac Analysis application is intended to be used for viewing, post-processing and quantitative evaluation of cardiac magnetic resonance data.

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."

Shanghai United Imaging Healthcare Co., Ltd.
Tel: +86 (21) 67076888 Fax：+86 (21) 67076889
www.united-imaging.com

510 (k) SUMMARY

1. Date of Preparation:

April 29, 2020

2. Sponsor Identification

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

Establishment Registration Number: 3011015597

Contact Person: Xin GAO
Position: Regulatory Affairs Manager
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade Name: uWS-MR
Common Name: MR Image Post-Processing Software
Model(s): uWS-MR

Regulatory Information
Classification Name: Picture archiving and communications 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: K183164
Device Name: uWS-MR

Reference Device#1
510(k) Number: K141480
Device Name: cvi42

Reference Device#2
510(k) Number: K153022
Device Name: Philips Medical Systems Nederland BV

5. Device Description

uWS-MR is a comprehensive software solution designed to process, review and analyze MR (Magnetic Resonance Imaging) studies. It can be used as a stand-alone SaMD or a post processing application option for cleared UIH (Shanghai United Imaging Healthcare Co.,Ltd.) MR Scanners. It can transfer images in DICOM 3.0 format over a medical imaging network or import images from external storage devices such as CD/DVDs or flash drives. 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 MIP and volume rendering and multiple statistical analysis including mean, maximum and minimum over a user-defined region is supported. A trained, licensed physician can interpret these displayed images as well as the statistics as per standard practice.

This Traditional 510(k) is to request modification for the cleared Picture archiving and communications system (uWS-MR) which have been cleared by FDA via K183164 on March 22, 2019.

The modifications performed on the uWS-MR (K183164) in this submission are due to the change of the advanced application (United Neuro) and addition of a new advanced application (MR Cardiac Analysis).

6. Indications for use

uWS-MR 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 MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages.

- The Dynamic application is intended to provide a general post-processing tool for time course studies.
- The Image Fusion application is intended to combine two different image series so that the displayed anatomical structures match in both series.
- MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data.
- The MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images.
- The MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images.
- The Brain Perfusion application is intended to allow the visualization of temporal variations in the dynamic susceptibility time series of MR datasets.
- MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images.
- The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels.
- The DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images.
- The United Neuro is intended to view, manipulate, and evaluate MR neurological images.
- The MR Cardiac Analysis application is intended to be used for viewing, post-processing and quantitative evaluation of cardiac magnetic resonance data.

7. Summary of Technological Characteristics

The technology characteristics of the modified uWS-MR, reflected in this 510(k) submission, do not alter the scientific technology of the devices and are substantially equivalent to those of the predicate devices.

The following tables compare the modified features, principles of operation, fundamental scientific technology and intended use of uWS-MR when compared to the predicate devices.

Table 1 Substantial equivalent discussion for basic functions

Item	**Proposed Device** uWS-MR	**Predicate Device** uWS-MR (K183164)	**Remark**
General			
Device Classification Name	Picture Archiving and Communications System	Picture Archiving and Communications System	Same
Product Code	QIH, 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	The proposed device includes more applications, which is discussed in the following chapters, than the predicate device. This difference will not impact the safety and effectiveness of the device.

Item	Proposed Device uWS-MR	Predicate Device uWS-MR (K183164)	Remark
Indications for use	uWS-MR 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 MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages. • The Dynamic application is intended to provide a general post-processing tool for time course studies. • The Image Fusion application is intended to combine two different image series so that the displayed anatomical structures match in both series. • MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the	uWS-MR 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 MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages. • The Dynamic application is intended to provide a general post-processing tool for time course studies. • The Image Fusion application is intended to combine two different image series so that the displayed anatomical structures match in both series. • MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the	The indications for use is supplemented. The proposed device includes more applications, which is discussed in the following chapters. This difference will not impact the safety and effectiveness of the device.

Item	Proposed Device uWS-MR	Predicate Device uWS-MR (K183164)	Remark
	complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data. • The MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images. • The MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images. • The Brain Perfusion application is intended to allow the visualization of temporal variations in the dynamic susceptibility time series of MR datasets. • MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images.	complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data. • The MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images. • The MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images. • The Brain Perfusion application is intended to allow the visualization of temporal variations in the dynamic susceptibility time series of MR datasets. • MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images.	

Item	Proposed Device uWS-MR	Predicate Device uWS-MR (K183164)	Remark
	• The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels. • The DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images. • The United Neuro is intended to view, manipulate, and evaluate MR neurological images. • The MR Cardiac Analysis application is intended to be used for viewing, post-processing and quantitative evaluation of cardiac magnetic resonance data.	• The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels. • The DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images. • The United Neuro is intended to view, manipulate, and evaluate MR neurological images.	
Specification			
Image communication	Yes	Yes	Same
Hardware /OS	Yes	Yes	Same
Patient Administration	Yes	Yes	Same
Review 2D	Yes	Yes	Same
Review 3D	Yes	Yes	Same
Filming	Yes	Yes	Same
Fusion	Yes	Yes	Same
Inner View	Yes	Yes	Same

Item	Proposed Device uWS-MR	Predicate Device uWS-MR (K183164)	Remark
Visibility	Yes	Yes	Same
ROI/VOI	Yes	Yes	Same
MIP Display	Yes	Yes	Same
Compare	Yes	Yes	Same
Report	Yes	Yes	Optimized function which will not impact the safety and effectiveness.

Table 2 Substantial equivalent discussion for MR Cardiac Analysis

Advanced Application	Function name		Proposed device uWS-MR	Reference Device#1 cvi42 (K141480)	Remark
Cardiac Analysis (New application)	Cardiac Function	Type of imaging scans	MR	MR	Same
		Image Loading and Viewing	Yes	Yes	Same
		LV Contour Segmentation	Yes	Yes	Same
		RV Contour Segmentation	Yes	Yes	Same
		Extent Definition	Yes	Yes	Same
		Parameters Calculation	Yes	Yes	Same
		BSA standardized	Yes	Yes	Same
		Polar Maps	Yes	Yes	Same
		Volume Curve	Yes	Yes	Same
		Result Saving	Yes	Yes	Same
		Report	Yes	Yes	Same

	Function name		**Proposed device** uWS-MR	**Reference Device#2** Philips IntelliSpace Cardiovascular (K153022)	**Remark**
	Flow Analysis	Type of imaging scans	MR	MR	Same
		Image Loading and Viewing	Yes	Yes	Same
		Plot vessel contour	Yes	Yes	Same
		Propagate Contour	Yes	Yes	Same
		Doppler Map	Yes	Yes	Same
		Parameters Calculation	Yes	Yes	Same
		Flow Curve	Yes	Yes	Same
		Result Saving	Yes	Yes	Same
		Report	Yes	Yes	Same

Advanced Application	**Function name**	**Proposed device** uWS-MR	**Predicate device** uWS-MR (K183164)	**Remark**
United Neuro (Modified Application)	Type of imaging scan	MR	MR	Same
	Motion correction	Yes	Yes	Same
	Functional activation calculation	Yes	Yes	Same
	Diffusion parameter analysis	Yes	Yes	Same
	Adjust display parameter	Yes	Yes	Same
	Fusion	Yes	Yes	Same
	Fiber tracking	Yes	Yes	Same
	Time-Intensity curve	Yes	Yes	Same
	ROI Statistics	Yes	Yes	Same
	Result Saving	Yes	Yes	Same
	Report	Yes	Yes	Same
	MR Segmentation	Yes	No	Note1

Note1: Provides the user-identified region segmentation, users can draw the region of interest manually, which does not affect 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 Verification and Validation
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 have been classified as a moderate level of concern (LOC). Those 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

Performance Evaluation Report for MR Cardiac Analysis

Other Standards and Guidance

- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016).
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2007).

- 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-MR was 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 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.