Shanghai United Imaging Healthcare Co., Ltd.
% Xin Gao
Regulatory Affairs Specialist
NO.2258 Chengbei Road, Jiading District
Shanghai, 201807
CHINA

March 22, 2019

Re: K183164
Trade/Device Name: uWS-MR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 14, 2019
Received: March 18, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K183164

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.

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

UNITED IMAGING

510 (k) SUMMARY

1. **Date of Preparation:**
November 12, 2018

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 Specialist
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: LLZ
Regulation Number: 21 CFR 892.2050
Review Panel: Radiology

4. **Identification of Predicate Device(s)**

Predicate Device
510(k) Number: K172999
Device Name: uWS-MR

Reference Device#1
510(k) Number: K133401
Device Name: syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General

Reference Device#2
510(k) Number: K090546
Device Name: Nordic Image Control and Evaluation (nordicICE) Software

Reference Device#3
510(k) Number: K143368
Device Name: GenIQ

Reference Device#4
510(k) Number: K151353
Device Name: syngo.MR Neurology, syngo.MR Oncology

5. Device Description

uWS-MR is a comprehensive software solution designed to process, review and analyze MR (Magnetic Resonance Imaging) studies. 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 subject device contains the following modifications/improvements in comparison to the predicate device uWS-MR：

1) Modified Indications for Use Statement;
2) Added some advanced applications:
    - DCE Analysis
    - United Neuro

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

7. Summary of Technological Characteristics

uWS-MR comprises the post-processing applications for viewing, manipulation, 3D visualization, post-processing and comparison of MR images. After importing the DICOM image data into the system, the operator is able to perform image browsing and processing and can further obtain advanced information. This is identical to the predicate device.

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

8. Substantially Equivalent (SE) Comparison

Both the subject and predicate device have the same general information, such as Device Classification Name, Product Code, Classification Panel, etc. and visualization and measurement technological features：

- Image communication
- Hardware /OS
- Patient Administration
- Review 2D
- Review 3D
- Filming
- Fusion
- Inner View
- Visibility

- ROI/VOI
- MIP Display
- Compare

The subject and predicate device also have the same advanced applications in following:

- MR Brain Perfusion
- MR Breast Evaluation
- MR Stitching
- MR Vessel Analysis
- MRS
- MR Dynamic
- MR MAPs

The differences between the subject and the predicate device are about advanced applications is as follows:

- The subject device has added 2 new features to the predicate device. Substantial equivalence of these 2 features between the subject and the corresponding reference device is also discussed in Chapter 3.
    - DCE Analysis
    - United Neuro

Table 1 Comparison of general information

Item	**Proposed Device** uWS-MR	**Predicate Device** uWS-MR (K172999)	**Remark**
General			
Device Classification Name	Picture Archiving and Communications System	Picture Archiving and Communications 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	The subject device includes more applications, which is discussed in the following sections, 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 (K172999)	Remark
Intended 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	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	The intended use is supplemented. The subject device includes more applications, which is discussed in the following sections. This difference will not impact the safety and effectiveness of the device.

Item	Proposed Device uWS-MR	Predicate Device uWS-MR (K172999)	Remark
	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.	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.	

Table 2 SE Discussion for added Advanced Applications

Application	**Function name**	**Proposed device** uWS-MR	**Reference Device#1** syngro.MR Tissue4D(K133401)	**Reference Device#2** Nordic Image Control and Evaluation (nordicICE) Software (K090546)	**Reference Device#3** GenIQ (K143368)	**Remark**
DCE Analysis	Type of imaging scans	MR	MR	MR	MR	Same
	Image Loading and Viewing	Yes	Yes	Yes	Yes	Same
	Motion Correction	Yes	Yes	/	/	Same
	Series Registration	Yes	Yes	/	/	Same
	Parametric Maps					
	.Ktrans	Yes	/	Yes	/	Same
	.kep	Yes	/	Yes	/	Same
	.ve	Yes	/	Yes	/	Same
	.vp	Yes	/	Yes	/	Same
	.iAUC	Yes	/	Yes	/	Same
	.Max Slop	Yes	/	/	Yes	Same
	.CER	Yes	/	/	Yes	Same
	ROI Analysis	Yes	Yes	/	/	Same
	Result Saving	Yes	Yes	/	/	Same
	Report	Yes	Yes	/	/	Same

Application	**Function name**	**Proposed device** uWS-MR	**Reference device#4:** Syngo.via (K151353)	**Remark**
United Neuro	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

9. 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). These documentations include:

• Software description
• Hazard Analysis
• Software requirements specification (SRS)
• Software Architecture Description
• Software Development Environment Description
• Software Verification and Validation
• Cyber security Documents

Animal Study

No animal study was required.

Clinical Studies
No clinical study was required.

Performance Verification

- Performance Evaluation Report For MR DCE
- Performance Evaluation Report For MR United neuro

Product 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.

10. 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.