November 7, 2018

Shanghai United Imaging Healthcare Co., Ltd.
℅ Shumei Wang
QM&RA VP
No.2258 Chengbei Road, Jiading District
Shanghai, 201807
CHINA

Re: K172999
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: October 9, 2018
Received: October 10, 2018

Dear Shumei Wang:

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
Robert Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172999

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.

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

K172999

1. **Date of Preparation:**
March 26, 2018

2. **Sponsor Identification**

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

Establishment Registration Number: Not yet registered or the Number

Contact Person: Shumei Wang
Position: QM&RA VP
Tel: +86-021-67076888-6776
Fax: +86-021-67076889
Email: shumei.wang@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: K123920
Device Name: syngo.via

Reference Device#1
510(k) Number: K151353
Device Name: Syngo.MR Neurology, Syngo.MR Oncology

Reference Device#2
510(k) Number: K130749
Device Name: syngo.MR General, syngo.MR Cardiology and syngo.MR Vascular

Reference Device#3
510(k) Number: K120315
Device Name: syngo.MR Spectroscopy

Reference Device#4
510(k) Number: K133401
Device Name: syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General

Reference Device#5
510(k) Number: K960265
Device Name: Advantage Windows with FuncTool Option

Reference Device#6
510(k) Number: K090546
Device Name: Nordic Image Control and Evaluation (nordicICE) Software

Reference Device#7
510(k) Number: K081985
Device Name: AW Server

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.

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.

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

The proposed device has similar indications for use and overall function and performs in a similar manner with respect to, display, review and processing applications with predicate device and reference devices.

Table 1 SE Discussion for basic functions

Item	Proposed Device uWS-MR	Predicate Device syngo.via(K123920)	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
Specification			
Image communication	Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image.	Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image.	Same
Hardware /OS	Windows 7	Windows 7	Same
Patient Administration	Display and manage the image data information of all patients stored in the database.	Display and manage the image data information of all patients stored in the database.	Same
Review 2D	2D Review consists of basic processing of the 2D images, e.g. rotation, scaling, translation, windowing, and measurements.	2D Review consists of basic processing of the 2D images, e.g. rotation, scaling, translation, windowing, and measurements.	Same
Review 3D	3D Review consist of functionalities for displaying and processing image in the 3D form, e.g. VR, CPR, MPR, MIP, etc. The module also includes tools for VOI analysis.	3D Review consist of functionalities for displaying and processing image in the 3D form, e.g. VR, CPR, MPR, MIP, etc. The module also includes tools for VOI analysis.	Same
Filming	Filming is a module dedicated for image printing. The print tools provide layout editing for both single images and series.	Filming is a module dedicated for image printing. The print tools provide layout editing for both single images and series.	Same
Fusion	Including Auto registration, Manual registration, Spot registration	Including Auto registration, Manual registration, Spot registration	Same
Inner View	Inner view the vessel , colon , trachea	Inner view the vessel , colon , trachea	Same
Visibility	User-defined the display property of fused image: Adjustment of preset of T/B value; Adjustment of the fused rate; Adjustment of pse	User-defined the display property of fused image: Adjustment of preset of T/B value; Adjustment of the fused rate; Adjustment of pse	Same

Item	Proposed Device uWS-MR	Predicate Device syngo.via(K123920)	Remark
ROI/VOI	Plotting ROI or VOI, and obtaining the maximum activity value, the minimum activity value, mean activity value, the volume/area of region, and the maximum diameter of volume, peak activity value;	Plotting ROI or VOI, and obtaining the maximum activity value, the minimum activity value, mean activity value, the volume/area of region, and the maximum diameter of volume, peak activity value;	Same
MIP Display	The image can be displayed as MIP and rotating play	The image can be displayed as MIP and rotating play	Same
Compare	Load two studies to compare.	Load two studies to compare.	Same

Table 2 SE Discussion for advanced applications

Application	Function name	Proposed device uWS-MR	Reference Device#1 Syngo.MR Neurology, Syngo.MR Oncology (K151353)	Reference Device#6 Nordic Image Control and Evaluation (nordicICE) Software (K090546)	Remark
MR Brain Perfusion	Type of imaging scans	MRI	MRI	/	Same
	Intended Body part	MR neurological images.	MR neurological images.	/	Same
	Rectify motion	Yes	Yes	/	Same
	Remove background	Yes	Yes	/	Same
	Arterial Select: Automatically or manually select arterial location.	Yes	Yes	/	Same
	Parametric Mapping Calculation	Yes	/	Yes	Same
	TIC Analysis	Yes	Yes	/	Same
	Save Image Data	Yes	Yes	/	Same
	Print Image Data	Yes	Yes	/	Same
	Report	Yes	Yes	/	Same

Application	**Function name**	**Proposed device** uWS-MR	**Reference Device#4** syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General (K133401)	**Reference Device#5** Advantage Windows with FuncTool Option (K960265)	**Remark**
MR Breast Evaluation	Type of imaging scans	MRI	MRI	MRI	Same
	Intended Body part	Breast	Breast	Breast	Same
	Automatic Subtraction	Yes	Yes	Yes	Same
	Motion Correction	Yes	Yes	Yes	Same
	TIC Analysis	Yes	Yes	Yes	Same
	Background Removal	Yes	Yes	Yes	Same
	TIC Analysis	Yes	Yes	Yes	Same
	Automatic Parameter Map Calculation	Yes	Yes	Yes	Same
	Save Image Data	Yes	Yes	Yes	Same
	Print Image Data	Yes	Yes	Yes	Same
	Report	Yes	Yes	Yes	Same

Application	**Function name**	**Proposed device** uWS-MR	**Reference Device#2** syngo.MR General, syngo.MR Cardiology and syngo.MR Vascular(K130749)	**Remark**
MR Stitching	Type of imaging scans	MRI	MRI	Same
	Intended Body part	WholeBody	WholeBody	Same
	Automatic Stitching	Yes	Yes	Same
	Manual Stitching	Yes	Yes	Same
	Homogenous Modification	Yes	Yes	Same
	Sharp/Smooth	Yes	Yes	Same
	Save Image Data	Yes	Yes	Same
	Print Image Data	Yes	Yes	Same
	Report	Yes	Yes	Same

Application	Function name	Proposed device uWS-MR	Reference Device#2 syngo.MR General, syngo.MR Cardiology and syngo.MR Vascular (K130749)	Reference Device#7 AW SERVER(K 081985)	Remark
MR Vessel Analysis	Type of imaging scans	MRI	MRI	/	Same
	Intended Body part	WholeBody	WholeBody	/	Same
	Automatic blood vessel center lines extraction	Yes	Yes	/	Same
	Vascular stenosis analysis:	Yes	/	Yes	Same
	Vascular display with MPR\CPR\VR\MIP	Yes	Yes	/	Same
	Save Image Data	Yes	Yes	/	Same
	Print Image Data	Yes	Yes	/	Same
	Report	Yes	Yes	/	Same

Application	Function name	Proposed device uWS-MR	Reference Device#3 syngo.MR Spectroscopy (K120315)	Remark
MRS	Type of imaging scans	MRI	MRI	Same
	Intended Body part	Brain	Brain	Same
	Single-voxel Spectrum Data Analysis	Yes	Yes	Same
	Chemical Shift Imaging Data	Yes	Yes	Same
	Protocol Management:	Yes	Yes	Same
	Statistics Analysis	Yes	Yes	Same
	Metabolite Pseudo-color Map:	Yes	Yes	Same
	Curve Peak Setting	Yes	Yes	Same
	Save Image Data	Yes	Yes	Same
	Print Image Data	Yes	Yes	Same
	Report	Yes	Yes	Same

Application	Function name	Proposed device	Reference Device#5	Remark

		uWS-MR	Advantage Windows with FuncTool Option (K960265)	
MR Dynamic MR MAPs	ADC and eADC Calculate	Yes	Yes	Same
	T1, T2, T2*/R2* Calculate	Yes	Yes	Same
	Background Removal	Yes	Yes	Same
	ROI Curves Analysis: Plot interested region, including correlated or non-correlated, symmetric or asymmetric, and get mean time-intensity curve	Yes	Yes	Same
	Statistic Table: Produce statistical table for parameters, and freely select to display items in demand.	Yes	Yes	Same
	DCE (Dynamic Contrast Enhance) customizes background pixel range calculation (Support to modify manually), and automatically provides parameter value, end-stage scanning value (Support to modify by need). The relative Parameter Maps includes PEI (Positive Enhanced Integration), TTP (Time to Peak), MSI (Maximum Slope of Increasing) and MTE (Mean Time to Enhance).	Yes	Yes	Same
	DSC (Dynamic Susceptibility Contrast-enhance) customizes background pixel range calculation (Support to modify manually), and automatically provides parameter value, end-stage scanning value (Support to modify by need). The relative Parameter Maps includes NEI (Negative Enhanced Integration), TTP (Time to Peak), MSD (Maximum Slop of Descending) and MTE (Mean Time to Enhance)	Yes	Yes	Same
	Save Image Data	Yes	Yes	Same
	Print Image Data	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 For MR Dynamic
- Performance Evaluation For MR Breast
- Performance Evaluation For MR Stitching
- Performance Evaluation For MR Brain Perfusion
- Performance Evaluation For MR Spectroscopy
- Performance Evaluation For MR Fusion
- Performance Evaluation For MR Inner View
- Performance Evaluation For MR Vessel
- Performance Evaluation For MR Maps

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.