October 27, 2022

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

Re: K220332
Trade/Device Name: uMR Omega with uWS-MR-MRS
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LLZ, QIH
Dated: September 23, 2022
Received: September 26, 2022

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220332

Device Name
uMR Omega, uWS-MR-MRS

Indications for Use *(Describe)*
The uMR Omega system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities.
These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.

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.

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510 (k) SUMMARY

1. Date of Prepared K220332

October 19, 2022

2. Sponsor Identification

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

Contact Person: Xin GAO
Position: Regulatory Affairs Specialist
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3. Identification of Proposed Device(s)

Trade Name: uMR Omega with uWS-MR-MRS
Common Name: Magnetic Resonance Diagnostic Device
Model: uMR Omega, uWS-MR
Product Code: LNH, LLZ, QIH
Regulation Number: 21 CFR 892.1000
Device Class: II

4. Identification of Predicate Devices(s)

Predicate Device
510(k) Number: K193200
Device Name: uMR Omega
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH

Reference Device #1
510(k) Number: K192601
Device Name: uWS-MR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: II
Product Code: LLZ, QIH

Reference Device #2
510(k) Number: K193176
Device Name: uMR 780
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH

5. Device Description

The uMR Omega is a 3.0T superconducting magnetic resonance diagnostic device with a 75cm size patient bore. It consists of components such as magnet, RF power amplifier, RF coils, gradient power amplifier, gradient coils, patient table, spectrometer, computer, equipment cabinets, power distribution system, internal communication system, and vital signal module etc. The uMR Omega Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.
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.
The uMR 780 is a 3.0T superconducting magnetic resonance diagnostic device with a 65cm size patient bore. It consists of components such as magnet, RF power amplifier, RF coils, gradient power amplifier, gradient coils, patient table, spectrometer, computer, equipment cabinets, power distribution system, internal communication system, and vital signal module etc. The uMR 780 Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

uMR Omega , uWS-MR and uMR 780 have been previously cleared by FDA via K193200 , K192601 and K193176.

The modification performed on the uMR Omega (K193200), uWS-MR (K192601) and uMR 780 (K193176) in this submission is due to the following changes that include:
(1). Addition of Radio Frequency Coils: Head & Neck Coil - 48, Spine Coil - 48, Head Coil - 64, SuperFlex Body - 24, SuperFlex Large - 12, SuperFlex Small -12.
(2). Addition and modification of pulse sequences
a) New sequences: gre_fact, asl_3d, gre_maps, fse_mars_sle, grase, fse_dwi, fse_arms_dwi, gre_fq, gre_bssfp_fi, epi_dwi_msh, gre_senc_spiral, gre_bssfp_ucs, gre_rufis.
b) Broadened application scope of Contrast characteristic for certain sequences: T1 mapping, T2 mapping, T2* mapping.
c) Added Associated options for certain sequences: QuietScan, Parallel imaging, MultiBand, Inversion Recovery.
d) Added Reconstruction method for certain sequences: AI-assisted Compressed Sensing, Compressed sensing.

e) Added Additional accessory equipment required for certain sequences: respiratory, cardiac gating.
f) Deletion of pulse sequence: fse_mx_mars.
(3). Addition of Imaging processing methods: Fat Analysis and Calculation Technique (FACT), Inline T1/T2* Map, Inline T2 Map, Arterial Spin Labeling (ASL), Flow Quantification (FQ), Cardiac T1 Mapping, Cardiac T2 Mapping, Cardiac T2* Mapping, DeepRecon.
(4). Addition of Spectroscopy Sequences and Post Processing Features: Liver, Prostate, Breast.
(5). Addition of New function: Remote Assistance, MR conditional implant mode.
(6). Addition of Support body parts for EasyScan: Shoulder, Abdomen, L-spine, T-spine.

These modifications do not affect the intended use or alter the fundamental scientific technology of the device.

6. Intended Use

The uMR Omega system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities.
These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.

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.

The uMR 780 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities.

These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.

7. Technological Characteristic

The differences from the predicate device are discussed in the comparison table in this submission is added below.

Table 1 Comparison of Hardware configuration

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K193200)	Remark
General			
Product Code	LNH	LNH	Same
Regulation No.	21 CFR 892.1000	21 CFR 892.1000	Same
Class	II	II	Same
Indications For Use	The uMR Omega system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic	The uMR Omega system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K193200)	Remark
	images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.	images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.	
Magnet system			
Field Strength	3.0 Tesla	3.0 Tesla	Same
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	75cm	75cm	Same
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	2.30ppm @ 50cm DSV 0.80ppm @ 45cm DSV 0.38ppm @ 40cm DSV 0.08ppm @ 30cm DSV 0.02ppm @ 20cm DSV 0.002ppm @ 10cm DSV	2.30ppm @ 50cm DSV 0.80ppm @ 45cm DSV 0.38ppm @ 40cm DSV 0.08ppm @ 30cm DSV 0.02ppm @ 20cm DSV 0.002ppm @ 10cm DSV	Same
Gradient system			
Max gradient amplitude	45mT/m	45mT/m	Same
Max slew rate	200T/m/s	200T/m/s	Same
Shielding	active	active	Same
Cooling	water	water	Same
RF system			

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K193200)	Remark
Resonant frequencies	128.23 MHz	128.23 MHz	Same
Number of transmit channels	2	2	Same
Number of receive channels	Up to 96	Up to 96	Same
Amplifier peak power per channel	18 kW	18 kW	Same
RF Coils			
Volume Transmit Coil	Yes	Yes	Same
Head & Neck Coil -24	Yes	Yes	Same
Body Array Coil - 12	Yes	Yes	Same
Breast Coil - 10	Yes	Yes	Same
Flex Coil Large - 8	Yes	Yes	Same
Flex Coil Small - 8	Yes	Yes	Same
Knee Coil - 12	Yes	Yes	Same
Lower Extremity Coil - 36	Yes	Yes	Same
Shoulder Coil - 12	Yes	Yes	Same
Small Loop Coil	Yes	Yes	Same
Spine Coil - 32	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
Cardiac Coil - 24	Yes	Yes	Same
Temporomandibular Joint Coil - 4	Yes	Yes	Same
Foot & Ankle Coil - 24	Yes	Yes	Same
Head Coil - 32	Yes	Yes	Same
Head Coil - 12	Yes	Yes	Same
Carotid Coil - 8	Yes	Yes	Same
Infant Coil - 24	Yes	Yes	Same
Body Array Coil - 24	Yes	Yes	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K193200)	Remark
Head & Neck - 48	Yes	No	The intended use of Head & Neck Coil - 48 is equivalent to previously cleared Head & Neck Coil - 24. More coil elements in the new coil can better cover the scanning parts.
Spine Coil - 48	Yes	No	The intended use of Spine Coil - 48 is equivalent to previously cleared Spine Coil - 32. More coil elements in the new coil can better cover the scanning parts.
Head Coil - 64	Yes	No	The intended use of Head Coil - 64 is equivalent to previously cleared Head Coil - 32. More coil elements in the new coil can better cover the scanning parts.
SuperFlex Body - 24	Yes	No	The intended use of SuperFlex Body - 24 is essentially identical to previously cleared Body Array Coil - 12. The differences are the number of channels of the coil and the material used on the surface of the coil. More coil elements in the new coil can better cover the scanning parts and the flexible material is beneficial to wrap the scanning parts.
SuperFlex Large - 12	Yes	No	The intended use of SuperFlex Large - 12 is essentially identical to previously cleared Flex Coil Large - 8. The differences are the number of channels of the coil and the material used on the surface of the coil. More coil elements in the new coil can better cover the scanning parts and the

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K193200)	Remark
			flexible material is beneficial to wrap the scanning parts.
SuperFlex Small - 12	Yes	No	The intended use of SuperFlex Small - 12 is essentially identical to previously cleared Flex Coil Small - 8. The differences are the number of channels of the coil and the material used on the surface of the coil. More coil elements in the new coil can better cover the scanning parts and the flexible material is beneficial to wrap the scanning parts.
Patient table			
Dimensions	width 640mm, height 880mm, length 2620mm	width 640mm, height 880mm, length 2620mm	Same
Maximum supported patient weight	310 kg	310 kg	Same
Accessories			
Vital Signal Gating	ECG, Peripheral Pulse Gating, Respiratory Gating	ECG, Peripheral Pulse Gating, Respiratory Gating	Same
Safety			
Electrical Safety	Comply with ES60601-1	Comply with ES60601-1	Same
EMC	Comply with IEC60601-1-2	Comply with IEC60601-1-2	Same
Max SAR for Transmit Coil	Comply with IEC 60601-2-33	Comply with IEC 60601-2-33	Same
Max dB/dt	Comply with IEC 60601-2-33	Comply with IEC 60601-2-33	Same
Biocompatibility	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K193200)	Remark
		sensitization (ISO 10993-10).	
Surface Heating	NEMA MS 14	ES 60601-1	The NEMA standards publication MS 14-2019 describes the procedure for heating RF coil heating under worst-case normal operating conditions. The results for the surface heating test showed that proposed devices perform as well as or better than predicate devices.

Table 2 provides the new application software features of the proposed device in comparison to the predicate device.

Table 2 Comparison of the new Application Software Features

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K193200)	Remark
Imaging Features			
Fat Analysis and Calculation Technique (FACT)	Yes	No	FACT is short for fat analysis and calculation technique and substantially equivalent to WFI. It not only separates water and fat signal and quantifies fat fraction and R2* mapping according to chemical shift effect and T2* effect.
Inline T1/T2* Mapping	Yes	No	Inline T1/T2* Mapping is substantially equivalent to T1/T2* Mapping processed by post-processing module. The map result displays inline without extra operation by post-processing module.
Inline T2 Mapping	Yes	No	Inline T2 Map is substantially equivalent to T2 Map processed by post-processing module. The map result displays inline without extra operation by post-processing module.
Arterial Spin Labeling (ASL)	Yes	No	ASL is substantially equivalent to FSE and uses extra arterial spin labeling preparation and imaging processing for cerebral blood flow (CBF) imaging without contrast agent.
Flow Quantification (FQ)	Yes	No	FQ is substantially equivalent to GRE and uses extra flow encoding and imaging processing for flow quantification.

Cardiac T1 Mapping	Yes	No	Cardiac T1 mapping is substantially equivalent to GRE and uses multiple TI acquisitions with IR preparation and imaging processing for cardiac T1 mapping.
Cardiac T2 Mapping	Yes	No	Cardiac T2 mapping is substantially equivalent to GRE and uses multiple T2-prep duration preparation acquisitions and imaging processing for cardiac T2 mapping.
Cardiac T2* Mapping	Yes	No	Cardiac T2* mapping is substantially equivalent to GRE and uses multiple TE acquisitions and imaging processing for cardiac T2* mapping.
DeepRecon	Yes	No	Note 1
Workflow Features			
Easy Scan	Yes	No	Easy Scan feature allows automatic slice positioning for Shoulder, Abdomen, L-spine and T-spine imaging. The positioning can also be adjusted manually by user. The final positioning effect is equivalent to manual operation without Easy Scan feature.
Function			
MR conditional implant mode	Yes	No	In MR conditional implant mode， user can set the safety conditions of the MR conditional implant, and uMR Omega system ensure the scanning complies with the conditions.
Remote Assistance	Yes	No	Remote Assistance intends for remote support and service.
Spectroscopy Sequences			
Liver Spectroscopy	Yes	No	Liver spectroscopy is substantially equivalent to Spectroscopy and uses multi-echo acquisition and post-processing instead of single echo for fat quantification of liver.
Prostate Spectroscopy	Yes	No	Prostate spectroscopy is substantially equivalent to Spectroscopy and uses characteristic metabolites detection post processing for prostate spectroscopy.
Breast Spectroscopy	Yes	No	Breast spectroscopy is substantially equivalent to Spectroscopy and uses characteristic metabolites detection post processing for breast spectroscopy.

Note 1	DeepRecon is a deep-learning based image processing algorithm for intelligent image de-noising and K-space-interpolation based image super-resolution. The training data of DeepRecon were collected from 264 volunteers. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulted in a total of 165,837 cases. In terms of the ground truth and input images in training dataset, the multiple-averaged images with high-resolution and high SNR were collected as the ground-truth images. The input images were generated from the ground-truth images by sequentially reducing the SNR and resolution of the ground-truth images. All data were manually quality controlled before included for training.

The DeepRecon has undergone performance testing on 77 US subjects with diverse demographic distributions covering various genders, age groups, ethnicities, and BMI groups (Table a).

Table a. DeepRecon American Volunteers' Demographic Distribution

Subjects' Characteristics	Total(N=77)
Gender	
Male	37
Female	40
Age	
18-29	14
30-44	30
45-64	24
>=65	9
Ethnicity	
White	36
Black	19
Asian	5
Hispanic (of any race)	17
Body Mass Index (BMI)	
Underweight (<18.5)	1
Healthy weight (18.5-24.9)	18
Overweight (25.0-29.9)	28
Class1 Obesity (30.0-34.9)	14
Class2 Obesity (35-39.9)	8
Class3 Obesity (>=40)	8

The independence of these testing datasets were ensured by collecting testing data from various clinical sites and during separated time periods and on subjects different from the training data. Thus, the testing data have no overlap with the training data and are completely independent. The acceptance criteria for performance testing and the corresponding testing results can be found in Table b**.**

Table b. The performance evaluation report criteria of DeepRecon

Evaluation Item	Acceptance Criteria	Test Result	Results
Image SNR	DeepRecon images achieve higher SNR compared to the images without DeepRecon (NADR)	NADR: 209.41±1.08 DeepRecon: 302.48±0.78	PASS
Image uniformity	Uniformity difference between DeepRecon images and NADR images under 5%	0.15%	PASS
Image contrast	Intensity difference between DeepRecon images and NADR images under 5%	0.9%	PASS

	Structure measurement	Measurements on NADR and DeepRecon images of same structures, measurement difference under 5%	0%	PASS

The DeepRecon has been validated to provide image de-nosing and super-resolution processing using various ethnicities, age groups, BMIs, and pathological variations. In addition, DeepRecon images were evaluated by American Board of Radiologists certificated physicians, covering a range of protocols and body parts. The evaluation reports from radiologists verified that DeepRecon meets the requirements of clinical diagnosis. All DeepRecon images were rated with equivalent or higher scores in terms of diagnosis quality.

Table 3 provides the new Post Processing Features of the proposed device in comparison to the Reference Device #1.

Table 3 Comparison of the new Post Processing Features

ITEM	**Function name**	**Proposed device uWS-MR**	**Reference Device #1 uWS-MR (K192601)**	**Remark**
MRS	Type of imaging scans	MRI	MRI	Same
	Intended Body part	Brain, Body	Brain	Provides spectroscopy protocol of the body including prostate, breast and liver, which does not affect safety and effectiveness.
	Single-voxel Spectrum Data Analysis	Yes	Yes	Same
	Chemical Shift Imaging Data	Yes	Yes	Same
	Protocol Management	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

Table 4 provides the new Image Processing Features of the proposed device in comparison to the reference device #2.

Table 4 Comparison of the new Image Processing Features

ITEM	**Proposed Device** uMR Omega	**Reference Device #2** uMR 780 (K193176)	**Remark**
Image Processing Features			
AI-assisted compressed sensing	Yes	Yes	Same
Inline T1/T2* Mapping	Yes	Yes	Same

Table 5 provide the Basic Functions of the Proposed Device uWS-MR in comparison to the reference device #1. All basic functions of uWS-MR are same as uWS-MR (K192601) in this submission.

Table 5 Comparison of the Basic Functions of uWS-MR

Item	**Proposed Device** uWS-MR	**Reference Device #1** uWS-MR (K192601)	**Remark**
General			
Device Classification Name	Medical image management and processing system	Medical image management and processing system	Same
Product Code	QIH LLZ	QIH LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Device Class	II	II	Same
Classification Panel	Radiology	Radiology	Same
Advanced Application	Yes	Yes	Same
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	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.	Same

Item	Proposed Device uWS-MR	Reference Device #1 uWS-MR (K192601)	Remark
	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 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.	

Item	Proposed Device uWS-MR	Reference Device #1 uWS-MR (K192601)	Remark
	• 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. • The MR Cardiac Analysis application is intended to be used for viewing, post-processing and quantitative evaluation of cardiac magnetic resonance data.	

Based on the comparison and analysis above, the proposed device has same intended use, similar performance, equivalence safety and effeteness in hardware and software as the predicate device. The differences above between the proposed device and predicate device do not affect the intended use, technology characteristics, safety and effectiveness. And no issues are raised regarding to safety and effectiveness.

8. Performance Data

The following performance data according to FDA guidances and Recognized Consensus Standards were provided in support of the substantial equivalence determination.

- ES 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment Part 1-2: General Requirements for basic safety and essential Performance
- IEC 60601-2-33 Ed. 3.1:2013, Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical

Devices - Part 10: Tests For Irritation And Skin Sensitization

- MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 6-2008(R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

Non-clinical testing were conducted to verify the features described in this premarket submission.

- Clinical performance evaluation
- Performance evaluation report for SENC(sequence: gre_senc_spiral), 3D ASL (asl3d sequence), uCS Cine, FACT, MultiBand, Quiet Scan, 2D Flow quantification, EasyScan, Inline T1/T2* Mapping, Inline T2 Mapping，AI-assisted Compressed Sensing (ACS), DeepRecon, Metal Artifact Reduction Sequence (MARS), Cardiac T1 Mapping, Cardiac T2 Mapping, Cardiac T2* Mapping.
- Performance testing for Spectroscopy: MRS Breast, MRS Prostate, MRS Fat Fraction.
- System Validation report: Remote Assistance, MR conditional implant mode.

The test results demonstrated that the device performs as expected and thus, it is substantial equivalent to the predicate devices to which it has been compared.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, we conclude that uMR Omega Magnetic Resonance Diagnostic Device with uWS-MR-MRS is substantially equivalent to the predicate device. It does not introduce new indications for use, and has the same technological characteristics and does not introduce new potential hazards or safety risks.