May 23, 2023

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

Re: K230152
Trade/Device Name: uMR Omega
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: April 24, 2023
Received: April 24, 2023

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)*
K230152

Device Name
uMR Omega

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.

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

April 24, 2023

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
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

3. Identification of Proposed Device(s)

Trade Name: uMR Omega
Common Name: Magnetic Resonance Diagnostic Device
Model: uMR Omega
Product Code: LNH
Regulation Number: 21 CFR 892.1000
Device Class: II

4. Identification of Predicate Devices(s)

Predicate Device
510(k) Number: K220332
Device Name: uMR Omega
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.

uMR Omega has been previously cleared by FDA via K220332.

The modification performed on the uMR Omega (K220332) in this submission is due to the following changes that include:

(1) Addition of the Radio Frequency Power Amplifier model: uXD2201.
(2) Addition of Radio Frequency Coils: Tx/Rx Knee Coil -24 and SuperFlex Body Wide - 24.
(3) Addition of VSM models: uVWMERP, uMVRX and mmw100.
(4) Addition and modification of pulse sequences
    a) New sequences: gre_snap, gre_quick_4dncemra, gre_trass, epi_se_mre, gre_fq.
    b) Added Associated options for certain sequences: T1Rho, CEST, FSP+ (eT1, eGM), silica gel imaging, mPLD, whole heart coronary angiography imaging.
    c) Name change of pulse sequence: gre (old name: gre_sp), gre_fine (old name: gre_bssfp_fi), gre_quick (gre_quick_wfi merge to gre_quick), gre_quick (gre_bloustracking merge to gre_quick).
(5) Addition of imaging processing methods: 4D Flow Quantification, Magnetic Resonance Elastography (MRE), SNAP, CEST, T1Rho, FSP+.
(6) Addition of Dockable Patient Table.
(7) Add the positioning workflow (uVision) with camera.
(8) Addition of Resoundant Acoustic Driver System for Magnetic Resonance Elastography (MRE).

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.

7. Technological Characteristic

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

Table 1 Comparison of Hardware configuration

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K220332)	Remark
General			
510(K) No.		K220332	

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K220332)	Remark
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 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.	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.	Same
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 (K220332)	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, 20 kW	18 kW	Note 1
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
Head & Neck Coil - 48	Yes	Yes	Same
Spine Coil - 48	Yes	Yes	Same
Head Coil - 64	Yes	Yes	Same
SuperFlex Body - 24	Yes	Yes	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K220332)	Remark
SuperFlex Large - 12	Yes	Yes	Same
SuperFlex Small - 12	Yes	Yes	Same
Tx/Rx Knee Coil - 24	Yes	No	Note 2
SuperFlex Body Wide - 24	Yes	No	Note 3
Patient table			
Dimensions	Patient Table: width 640mm, height 880mm, length 2620mm Dockable Patient Table: width 826mm, height 880mm, length 2578mm	width 640mm, height 880mm, length 2620mm	Note 4
Maximum supported patient weight	Patient Table: 310 kg Dockable Patient Table: 310kg	310 kg	Same
Accessories			
Vital Signal Gating	Wireless UIH Gating Unit 453564324621 ECG module 989803163121 SpO2 module 989803163111 (alternative)	Wireless UIH Gating Unit 453564324621 ECG module 989803163121 SpO2 module 989803163111 (alternative)	Same
	ECG, Rrespiration and pulse module uVWMERP Wireless gating trigger unit uMVRX (alternative)	/	Note 5
	Respiration module mmw100 (optional)	/	Note 6
uVision			
Max View Angle	75°	/	Note 7
Positioning Error	≤±5cm	/	Note 7
Safety			
Electrical Safety	Comply with ES 60601-1	Comply with ES 60601-1	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K220332)	Remark
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	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 sensitization (ISO 10993-10).	Same
Surface Heating	NEMA MS 14	NEMA MS 14	Same

Note 1	This submission adds a new radio frequency power amplifier model (uXD2201), which increases the amplifier peak power. The increase of peak output power is to reserve power margin for the magnetic resonance imaging system to better adapt to the scanning of patients with large loads, which is beneficial to the effectiveness of the system.
Note 2	The intended use of Tx/Rx Knee Coil is essentially identical to previously cleared Knee Coil -12. The first difference is that the Tx/Rx Knee Coil is of a 16 Legs High-Pass Birdcage used for transmitter coil. The second difference is the number of channels of the receiver coil.
Note 3	The intended use of Super Flex Wide - 24 is essentially identical to previously cleared Body Array Coil - 24. The differences are the material used on the surface of the coil. The flexible material is beneficial to wrap the scanning parts.
Note 4	This submission adds Dockable Patient Table to facilitate patient transfer.
Note 5	Compared to the predicate device, the proposed device add an alternative VSM model (include uVWMERP and uMVRX). The trigger method, principle, connection mode, installation position and other aspects of this model are completely consistent with the original model.
Note 6	Compared to the predicate device, the proposed device adds a respiratory gating mmw100 to monitor patient respiration. Compared with contact respiratory gating, mmw100 eliminates the operation of patient binding before scan, thus improving patient scan comfort.
Note 7	This submission adds a new positioning method using uVision to automatically move the located position to the isocenter of the magnet. This method reduces the steps of positioning and improves the previous cumbersome operation mode.

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 (K220332)	Remark
Image Processing Features			
4D Flow Quantification	Yes	No	4D Flow Quantification is substantially equivalent to GRE and uses extra three direction flow encoding gradients and repeats several times acquisition, and then uses specific imaging processing for

			4D (3D space directions and 1D time direction) flow quantification.
Magnetic Resonance Elastography (MRE)	Yes	No	Magnetic Resonance Elastography (MRE) is substantially equivalent to EPI_SE and uses extra motion encoding gradient to capture micro shear wave motion induced by vibration device and specific imaging processing for stiffness quantification.
SNAP	Yes	No	SNAP is substantially equivalent to GRE with two TI acquisitions and uses specific imaging processing to attain Simultaneous Non-contrast Angiography and intraPlaque hemorrhage images.
CEST	Yes	No	CEST is substantially equivalent to FSE_MX and uses extra chemical exchange saturation preparation pulse with different resonance frequencies to attain Z-spectrum and final CEST image.
T1Rho	Yes	No	T1Rho is substantially equivalent to GRE or FSE_MX and uses extra spin lock preparation pulse to attain T1Rho quantification mapping.
FSP+	Yes	No	FSP+ is substantially equivalent to FSP and acquires one more TI images. According to two TI images, eT1 (T1 Enhanced) and eGM (Gray Matter Enhanced) images can be attained by specific image processing.

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: 4D Flow (sequence: gre_fq); Magnetic Resonance Elastography (sequence: epi_se_mre); CEST (sequence: fse_mx); T1rho (sequence: gre, fse_mx); mPLD ASL (sequence: asl_3d); silica gel imaging (sequence: fse, fse_arms, fse_ssh).

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 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.