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

March 27, 2020

Re: K193200
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: March 11, 2020
Received: March 12, 2020

Dear Xin Gao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193200

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 K193200

1. Date of Prepared

March 11, 2020

2. Sponsor Identification

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3. Identification of Proposed Device(s)

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

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K191157
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 ultra-wide patient bore size design. 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.

6. 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.

7. Technological Characteristic

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

ITEM	Proposed Device uMR Omega	Predicate Device uMR 780 (K191157)	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 images， and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived	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	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR 780 (K191157)	Remark
	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.	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	65cm	Larger bore size for patients comfort during scanning without compromising other imaging functions.
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	2.3ppm @ 50cm DSV 0.8ppm @ 45cm DSV 0.38ppm @ 40cm DSV 0.08ppm @ 30cm DSV 0.02ppm @ 20cm DSV 0.002ppm @ 10cm DSV	2.4ppm @ 50cm DSV 0.8ppm @ 45cm DSV 0.39ppm @ 40cm DSV 0.11ppm @ 30cm DSV 0.038ppm @ 20cm DSV 0.002ppm @ 10cm DSV	In order to support larger bore size, uMR Omega system has a bigger magnet design. Compared with the predicate device, the size and 5-gauss line range is larger. The homogeneity of the magnet is equal or better at typical DSVs thus clinical scanning is not limited compared to predicate device.
Gradient system			
Max gradient amplitude	45mT/m	42mT/m	The higher Maximum Gradient Strength allows uMR Omega to achieve the shorter TE time than predicate device in certain imaging sequence. The system effectiveness and safety were verified by the third party report.
Max slew rate	200T/m/s	200T/m/s	Same
Shielding	active	active	Same
Cooling	water	water	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR 780 (K191157)	Remark
RF system			
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 48	More receive channels allow uMR Omega to use new high-channel count and bigger coverage receive coils.
Amplifier peak power per channel	18 kW	18 kW	Same
RF Coils			
Head & Neck Coil - 24	Yes	Yes	Same
Head Coil - 12	Yes	Yes	Same
Head Coil - 32	Yes	Yes	Same
Carotid Coil - 8	Yes	Yes	Same
Temporomandibular Joint Coil - 4	Yes	Yes	Same
Infant Coil - 24	Yes	Yes	Same
Spine Coil - 32	Yes	Yes	Same
Body Array Coil - 12	Yes	Yes	Same
Cardiac Coil - 24	Yes	Yes	Same
Flex Coil Large - 8	Yes	Yes	Same
Flex Coil Small - 8	Yes	Yes	Same
Breast Coil - 10	Yes	Yes	Same
Shoulder Coil - 12	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
Knee Coil - 12	Yes	Yes	Same
Lower Extremity Coil - 36	Yes	Yes	Same
Small Loop Coil	Yes	Yes	Same
Foot & Ankle Coil - 24	Yes	Yes	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR 780 (K191157)	Remark
Body Array Coil - 24	Yes	No	The intended use is equivalent to previously cleared Body Array Coil -12. More coil elements in the new coil allow larger coverage for bigger patient.
Patient table			
Dimensions	width 640mm, height 880mm, length 2620mm	width 640mm, height 880mm, length 2620mm	Same
Maximum supported patient weight	310 kg	250kg	Increased table supporting weight allows bigger and heavier patient to be scanned.
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 sensitization (ISO 10993-10).	Same

The proposed device and the predicate device are the same in regard to most of application features.

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

Table 2 Comparison of Application Software Features

ITEM	Proposed Device uMR Omega	Predicate Device uMR 780 (K191157)	Remark
Imaging Features			
Non-uniformity Correction	Yes	Yes	Same
Distortion Correction	Yes	Yes	Same
Image Filter	Yes	Yes	Same
Water-Fat Imaging (WFI)	Yes	Yes	Same
Susceptibility Weighted Imaging (SWI)	Yes	Yes	Same
Phase Contrast Imaging (PC)	Yes	Yes	Same
Gradient Echo Train Imaging (GETI)	Yes	Yes	Same
Apparent Diffusion Coefficient (ADC)	Yes	Yes	Same
Phase Sensitive Inversion Recovery (PSIR)	Yes	No	PSIR is substantially equivalent to conventional inversion recover y (IR) and uses phase sensitive rec onstruction to produce real image instead of magnitude image.
Computed DWI (cDWI)	Yes	No	cDWI calculates and outputs diffusion-weighted images with user-input b-values and is substantially equivalent to conventional DWI.
Susceptibility Weighted Imaging Plus (SWI+)	Yes	No	SWI+ is substantially equivalent to SWI and uses multi-echo in acquisition and reconstruction instead of single echo.
Workflow Features			
Easy Scan	Yes	No	Easy Scan feature allows automatic slice positioning for head, cardiac, c-spine and knee imaging. The positioning can also be adjusted manually from user. The final positioning effect is equivalent to manual operation without Easy Scan feature.

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. Substantial Equivalence

Summary of Non-Clinical Tests:

The following testing was conducted on the uMR Omega Magnetic Resonance Diagnostic Device as the predicate device:

- ES60601-1:2005/(R)2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- 60601-2-33 Ed. 3.2:2015 Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic
- IEC 60825-1 Edition 2.0 2007-03, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
- 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(R2014), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 2-2008(R2014), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- MS 3-2008(R2014), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- MS 6-2008(R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- MS 8-2016, Characterization Of The Specific Absorption Rate For Magnetic Resonance Imaging Systems
- MS 9-2008(R2014), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images

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

Summary of Clinical Tests:

- A volunteer study was used to determine the safety limits associated with gradient-induced nerve stimulation.
- Sample clinical images were provided to support the ability of uMR Omega to generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

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 concludes 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.