April 26, 2024

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

Re: K233673
Trade/Device Name: uMR Jupiter
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: March 11, 2024
Received: March 11, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233673

Device Name

uMR Jupiter

Indications for Use *(Describe)*

uMR Jupiter 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 device is intended for patients > 20 kg/44 lbs.

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 Preparation

November 15, 2023 K233673

2. Sponsor Identification

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

Contact Person: Xin GAO
Position: Regulatory Affair Manager
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3. Identification of Proposed Device

Trade Name: uMR Jupiter
Common Name: Magnetic Resonance Imaging System
Model: uMR Jupiter

Regulatory Information
Regulation Number: 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Review Panel: Radiology

4. Identification of Primary/Reference Device(s)

Predicate Device

510(k) Number: K230152
Device Name: uMR Omega
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Review Panel: Radiology

5. Device Description

uMR Jupiter is a 5T superconducting magnetic resonance diagnostic device with a 60cm size patient bore and 8 channel RF transmit system. 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. uMR Jupiter is designed to conform to NEMA and DICOM standards.

6. Indications for Use

uMR Jupiter 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 device is intended for patients > 20 kg/44 lbs.

7. Comparison of Technological Characteristics with the Predicate Device

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 Jupiter	Predicate Device uMR Omega	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 Jupiter 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	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	Note 1

ITEM	Proposed Device uMR Jupiter	Predicate Device uMR Omega	Remark
	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 device is intended for patients > 20 kg/44 lbs.	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	5.0 Tesla	3.0 Tesla	Note 2
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	60 cm	75 cm	Note 3
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	≤ 1.3 ppm @ 50cm DSV ≤ 0.45 ppm @ 45cm DSV ≤ 0.19 ppm @ 40cm DSV ≤ 0.08 ppm @ 30cm DSV ≤ 0.015 ppm @ 20cm DSV ≤ 0.0009 ppm @ 10cm DSV	≤ 2.30 ppm @ 50cm DSV ≤ 0.80 ppm @ 45cm DSV ≤ 0.38 ppm @ 40cm DSV ≤ 0.08 ppm @ 30cm DSV ≤ 0.02 ppm @ 20cm DSV ≤ 0.002 ppm @ 10cm DSV	Note 4
Gradient system			
Max gradient amplitude	120 mT/m	45 mT/m	Note 5
Max slew rate	200 T/m/s	200 T/m/s	Same
Shielding	active	active	Same
Cooling	water	water	Same
RF system			
Resonant frequencies	210.794 MHz	128.23 MHz	Note 6
Number of transmit channels	8	2	Note 7
Amplifier peak power per channel	8 kW	18 kW or 20 kW	

ITEM	Proposed Device uMR Jupiter	Predicate Device uMR Omega	Remark
Number of receive channels	96	Up to 96	Note 8
RF Coils			
SuperFlex Small-24	Yes	SuperFlex Small-12	Note 9
Tx/Rx Head Coil -48	Yes	Head Coil -32	Note 10
Tx/Rx Knee Coil - 24	Yes	Yes	Note 11
SuperFlex Body - 24	Yes	Yes	
Head & Neck Coil - 48	Yes	Yes	
Spine Coil - 48	Yes	Yes	
Patient table			
Dimensions	W×H×L: 640 mm×1025 mm× 2620 mm	W×H×L: 640 mm×880 mm× 2620 mm	Note 12
Maximum supported patient weight	310 kg	310 kg	Same
Accessories			
Vital Signal Gating	Support ECG/Respiratory/Pulse signal triggering the scan	Support ECG/Respiratory/Pulse signal triggering the scan	Same

Table 2 Comparison of the Application Software Features

ITEM	Proposed Device uMR Jupiter	Predicate Device uMR Omega	Remark
Imaging Features			
Non-uniformity Correction	Yes	Yes	Same
Distortion Correction	Yes	Yes	Same
Image Filter	Yes	Yes	Same
SWI (Susceptibility Weighted Imaging)	Yes	Yes	Same
PC (2D/3D Phase Contrast)	Yes	Yes	Same

GETI (Gradient Echo Train Imaging)	Yes	Yes	Same
ADC (Apparent Diffusion Coefficient)	Yes	Yes	Same
FACT (Fat Analysis and Calculation Technique)	Yes	Yes	Same
PSIR (Phase Sensitive Inversion Recovery)	Yes	Yes	Same
cDWI (Computed DWI)	Yes	Yes	Same
Inline T1 Mapping	Yes	Yes	Same
Inline T2* Mapping	Yes	Yes	Same
Inline T2 Mapping using SEME	Yes	Yes	Same
Inline T2 Mapping using MASS	Yes	No	Note 13
SWI+ (Susceptibility Weighted Imaging Plus)	Yes	Yes	Same
3D ASL (Arterial Spin Labeling)	Yes	Yes	Same
2D Flow (2D Flow Quantification)	Yes	Yes	Same
CEST (3D Chemical Exchange Saturation Transfer)	Yes	Yes	Same
T1rho (T1rho Quantitative Mapping Imaging)	Yes	Yes	Same
FSP+ (Fast Spoiled Gradient Echo Plus)	Yes	Yes	Same
CASS (Constructive Acquisition of Steady State)	Yes	No	Note 14
PASS (Pair-Echo Acquisition of Steady State)	Yes	No	Note 15
SNAP (Simultaneous Non-contrast Angiography and Intraplaque Hemorrhage)	Yes	Yes	Same
MultiBand	Yes	Yes	Same
Function			
Remote Assistance	Yes	Yes	Same
Spectroscopy Sequences			
Brain MRS	Yes	Yes	Same
Liver MRS	Yes	Yes	Same
Prostate MRS	Yes	Yes	Same
Workflow Features			
MoCap-Monitoring (Motion Capture Monitoring)	Yes	No	Note 16

Image Reconstruction Features			
ACS (AI-assisted Compressed Sensing)	Yes	Yes	Same
uCS (united Compressed Sensing)	Yes	Yes	Same

Note 1	The proposed device includes enhancements to the software that controls Specific Absorption Rate (SAR) based on simulations for human at least 20kg. Therefore, it is used for patient > 20 kg/44 lbs. The difference did not raise new safety and effectiveness concerns.
Note 2	The static field strength of the proposed device is different from the predicate device, but the basic imaging characteristics are consistent. The difference did not raise new safety and effectiveness concerns.
Note 3	The patient-accessible bore dimension of the proposed device is smaller than that of the predicate device, which satisfies the clinical applications. The difference did not raise new safety and effectiveness concerns.
Note 4	Magnet Homogeneity of the proposed device is better than that of the predicate device. Magnet homogeneity contributes to image quality. The proposed device with better magnet homogeneity is benefit for image quality. The difference did not raise new safety and effectiveness concerns.
Note 5	The max gradient amplitude of the proposed device is larger than that of the predicate device. Peripheral nerve stimulation and cardiac stimulation was controlled according to IEC 60601-2-33. The difference did not raise new safety and effectiveness concerns.
Note 6	The difference in the resonant frequencies of the proposed device and the predicate device is due to the difference in field strength. The difference did not raise new safety and effectiveness concerns.
Note 7	The transmit channel number of the proposed device is more than that of the predicate device. More transmit channels, better B1 uniformity. The local SAR was monitored to ensure patients' safety. The difference did not raise new safety and effectiveness concerns.
Note 8	The number of receive channels of proposed device is 96. The number of receive channels of predicate device is 48 or 96. The number of receive channels of proposed device is the same as one configuration of uMR Omega. The difference did not raise new safety and effectiveness concerns.
Note 9	The intended use of SuperFlex Small-24 is equivalent to previously cleared SuperFlex Small-12. The difference between them is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.
Note 10	The intended use of Tx/Rx Head Coil -48 is equivalent to previously cleared Head Coil -32. There are two differences between them. One is that Tx/Rx Head Coil -48 can be used as a transmitter coil and SAR is controlled. The other one is that the receiver channel number of Tx/Rx Head Coil -48 is more than that of Head Coil -32. The difference did not raise new safety and effectiveness concerns.
Note 11	These coils were modified to adapt the frequency of the proposed device. The difference did not raise new safety and effectiveness concerns.
Note 12	The height of the patient table of the proposed device is higher than that of the predicate device, which can satisfy clinical application. The difference did not raise new safety and effectiveness concerns.

Note 13	MASS is substantially equivalent to GRE and acquires three different types (lower order SSFP_FID, SSFP_SE and higher order SSFP_FID) of echo images and achieves T2 mapping image by an iteration and search method. The difference did not raise new safety and effectiveness concerns.
Note 14	CASS is substantially equivalent to BSSFP and acquires two different phase cycling angle images and combines them by MIP operation to reduce dark band artifacts. The difference did not raise new safety and effectiveness concerns.
Note 15	PASS is substantially equivalent to GRE and acquires two different type (SSFP_FID and SSFP_SE) of echo image and combines them to achieve hybrid contrast image. The difference did not raise new safety and effectiveness concerns.
Note 16	MoCap-Monitoring is a motion monitoring module which is periodic and is inserted into a pulse sequence. It can realize real-time motion monitoring in imaging scanning and provides an alert when motion occurs. The difference did not raise new safety and effectiveness concerns.

8. Performance Date

The following testing was conducted on uMR Jupiter and were provided in support of the substantial determination.

Non-Clinical Testing

Non-clinical testing including image performance tests were conducted for uMR Jupiter to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device.

UNITED IMAGING HEALTHCARE claims conformance to the following standards and guidance:

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI/AAMIES60601-1: 2005/ (R) 2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012) [IncludingAmendment2(2021)]Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 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: 2014, Edition 3.0, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-6:2010+A1:2013+A2:2020, Edition 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential

performance - Collateral standard: Usability.

- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- IEC 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.
- NEMA MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2-2008(R2020), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- NEMA MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 6-2008(R2014, R2020), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- NEMA MS 8-2016, Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- NEMA MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA MS 10-2010, Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging.
- NEMA MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- IEC /TR 60601-4-2: 2016, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software

- NEMA PS 3.1-3.20(2022d): Digital Imaging and Communications in Medicine (DICOM)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Biocompatibility

- ISO 10993-5: 2009, Edition 3.0, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: 2021, Edition 4.0, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23: 2021, Edition 1.0, Biological evaluation of medical devices - Part

10: Tests for irritation.

- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Other Standards and Guidance

- ISO 14971: 2019, Edition 3.0, Medical Devices – Application of risk management to medical devices
- Code of Federal Regulations, Title 21, Part 820 - Quality System Regulation
- Code of Federal Regulations, Title 21, Subchapter J - Radiological Health

Performance Verification

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

- Performance evaluation report for ACS, 3D ASL, MoCap-Monitoring, FACT, 2D Flow, CEST, T1rho, Multiband, Inline T1 mapping, Inline T2 mapping and Inline T2* mapping.
- Performance evaluation report for Spectroscopy: Liver MRS, Prostate MRS, Brain MRS
- A volunteer study was conducted to determine the nerve stimulation thresholds used to limit the gradient system output. The observed parameters were used to set the PNS (Peripheral Nerve Stimulation) threshold level which is required in IEC 60601-2-33.
- Sample clinical images for all clinical sequences and coils were reviewed by three U.S. board-certified radiologists comparing the proposed device and predicate device. It was shown that the proposed device can generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

Summary of the Machine Learning Algorithm

- ACS

ACS is an acceleration reconstruction technique. By adding one more regularization term from AI module, ACS is a slight extension of CS (Compressed Sensing).

The training dataset of AI module in ACS was collected from a variety of anatomies, image contrasts, and acceleration factors. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulting in a large number of cases. Fully-sampled k-space data were collected and transformed to image space as the ground-truth. The input data were generated by sub-sampling the fully-sampled k-space data with different parallel imaging acceleration factors and partial Fourier factors. All data were manually quality controlled before included for training.

The training and test datasets are collected from 35 volunteers, including 24 males and 11 females, ages ranging from 18 to 60. The samples from these volunteers are distributed randomly into training and test datasets. The validation dataset is collected from 15 volunteers, including 10 males and 5 females, whose ages range from 18 to 60.

ACS has undergone performance testing on 25 subjects coming from different countries with diverse demographic distributions covering various genders, age groups, ethnicities, and BMI groups (Table 6). Phantom test has also been performed for ACS to verify its performance.

Table 6 Distribution of volunteer dataset

Gender	
Male	15
Female	10
Age	
18-28	5
29-40	7
>41	13
Ethnicity	
White	4
Asian	21
Body Mass Index (BMI)	
Underweight (<18.5)	2
Healthy weight (18.5-24.9)	18
Overweight and obesity (>24.9)	5

The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data is entirely independent and does not share any overlap with the training data.

The ACS on uMR Jupiter was shown to perform better than CS by measuring SNR and resolution using images from various ethnicities, age groups, BMIs, and pathological variations. Meanwhile, results from the tests also demonstrated that ACS maintained image qualities, such as contrast and uniformity, as compared against fully sampled data as golden standards. The test results demonstrate that ACS on uMR Jupiter performs equivalently to that on uMR Omega. The structure measurements on paired images verified that ACS and fully sampled images of same structures were significantly the same.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uMR Jupiter was found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusions

Based on the comparison and analysis above, the proposed device has similar indications for use, performance, safety equivalence, and effectiveness 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. The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.