Shanghai United Imaging Healthcare Co.,Ltd.
Shumei Wang
Qm&ra VP
No.2258 Chengbei Road., Jiading Industrial District
Shanghai, 201807
CHINA

June 6th, 2018

Re: K180926
Trade/Device Name: uMR 560
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: April 6, 2018
Received: April 9, 2018

Dear Shumei Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180926

Device Name
uMR 560

Indications for Use *(Describe)*
The uMR 560 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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SECTION 7

510(k) Summary

510 (k) SUMMARY

1. **Date Prepared [21 CFR 807.92(a)(1)]**
   March 16, 2018

2. **General Information [21 CFR 807.92(a)(1)]**

Manufacturer: Shanghai United Imaging Healthcare Co., Ltd
2258 Chengbei Rd., Jiading District, Shanghai, 201807

Contact Person: Shumei Wang
QM&RA VP
Tel: +86 (21) 67076888-6776
Fax: +86-021-67076889
Email: shumei.wang@united-imaging.com

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	uMR 560
Common Name:	Magnetic Resonance Diagnostic Device
Model:	uMR 560
Product Code:	LNH
Regulation Number:	892.1000
Device Class:	II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

The identification of predicates device within this submission is as follow:

Predicate Device
Manufacturer: SIEMENS AG
Device Name: MAGNETOM AREA
Product Code: LNH
Device Class: II
Regulation Number: 21 CFR 892.1000
FDA 510 (k) #: K132951

5. **Device Description [21 CFR 807.92(a)(4)]**

The uMR 560 is a 1.5T superconducting magnetic resonance diagnostic device with a

60cm 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 560 Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

6. Intended Use [21 CFR 807.92(a)(5)]

The uMR 560 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 [21 CFR 807.92(a)(6)]

The uMR 560 has the same major technological characteristics as the predicate device. The differences from the predicate device including patient bore size, high order shimming configuration, interventional usage, RFPA power and external triggering function are discussed in the comparison table in this submission. The same scientific technology theory, similar physical design, same coil applications and functionalities are applied to both the uMR 560 and predicate device. The technical characteristic differences do not affect the safety and effectiveness of the uMR 560 for intended use.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Summary of Non-Clinical Tests:
The following testing was conducted on the uMR 560 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 3.0 2007-03, 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. 3.1:2013, 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 5-2010, 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 8-2008, 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 560 to generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

9. Conclusion [21 CFR 807.92(b)(3)]

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 560 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.