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

May 29, 2019

Re: K191157
Trade/Device Name: uMR 780, uMR 790
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: April 30, 2019
Received: May 1, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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

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)*
K191157

Device Name
uMR 780, uMR 790

Indications for Use *(Describe)*
The uMR 780/uMR790 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) SUMMARY K191157

1. Date of Prepared

April 30, 2019

2. Sponsor Identification

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3. Identification of Proposed Device(s)

Trade Name: uMR 780, uMR 790
Common Name: Magnetic Resonance Diagnostic Device
Model(s): uMR 780, uMR 790
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 #1
510(k) Number: K181370
Device Name: uMR 780
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH

Predicate Device #2
510(k) Number: K181371
Device Name: uMR 790
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH

Reference Device

510(k) Number: K183186
Device Name: Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil - 24
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: MOS

5. Device Description

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.

The uMR 790 is a 3.0T 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 790 Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

The modification performed on the previously cleared devices (K181370 for uMR 780 and K181371 for uMR 790) is due to the modification of magnet. The modification, which do not affect the intended use or alter the fundamental scientific technology of the device, is following:

- modify magnet with a new model number;

In addition, seven coils which have been previously cleared by FDA via K183186 (Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil – 24) are added in this submission.

6. Indications for Use

The uMR 780/uMR 790 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 technology characteristics of the modified uMR 780 and uMR 790, reflected in this 510(k) submission, do not alter the scientific technology of the devices and are substantially equivalent to those of the predicate devices.

8. Non-Clinical Tests

The following testing was conducted on the proposed devices:

- Signal to Noise Ratio
- Geometric Distortion
- Image Uniformity
- Magnetic Field Homogeneity
- Magnetic Field Decay
- IEC 60601-2-33 Ed. 3.2 B:2015, Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic

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.

9. Clinical Tests

No clinical testing was conducted on the proposed devices.

10. 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 the modified uMR 780 and uMR 790 Magnetic Resonance Diagnostic Device are substantially equivalent to the predicate devices. It does not introduce new indications for use, and has the same technological characteristics and does not introduce new potential hazards or safety risks.