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

April 20, 2020

Re: K200024
Trade/Device Name: uMR 570
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: April 3, 2020
Received: April 7, 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)*

K200024

Device Name
uMR 570

Indications for Use *(Describe)*

The uMR 570 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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UNITED IMAGING

510 (k) SUMMARY

1. Date of Prepared

April 03, 2020

2. Sponsor Identification

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3. Identification of Proposed Device(s)

Trade Name: uMR 570
Common Name: Magnetic Resonance Diagnostic Device
Model: uMR 570
Product Code: LNH
Regulation Number: 892.1000
Device Class: II

4. Identification of Predicate Devices(s)

Predicate Device
510(k) Number: K180925
Device Name: uMR 570
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH

5. Device Description

The uMR 570 is a 1.5T superconducting magnetic resonance diagnostic device with a 70cm 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 570 Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM

standards.

uMR 570 has been previously cleared by FDA via K180925.

The modification performed on the uMR 570(K180925) in this submission is due to the following changes that include:

1. Addition of Radio Frequency Coils: Head Coil-24, Head Coil-12, Carotid Coil-8
2. Addition and modification of pulse sequences
   a) New sequences: gre_quick_wfi, hise, gre_quick_4dcemra, gre_ute, gre_maps
   b) Broadened application scope of Contrast characteristic for certain sequences: T1,T2, Pd, T2/T1
   c) Added certain sequences Associated options: dark blood, navigator, multi-echo , reduced-FOV, cDWI
   d) Added Reconstruction method for certain sequences: compressed sensing
3. Addition of imaging processing methods: FACT(Fat Analysis and Calculation Technique), PSIR (Phase Sensitive Inversion Recovery), cDWI (Computed DWI), Inline T1/T2* Map, SWI+ (Susceptibility Weighted Imaging Plus)

These modifications do not affect the intended use or alter the fundamental scientific technology of the device.

6. Intended Use

The uMR 570 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.

Table 1 Comparison of Hardware configuration

ITEM	Proposed Device uMR 570	Predicate Device uMR 570 (K180925)	Remark
General			
Product Code	LNH	LNH	Same
Regulation No.	21 CFR 892.1000	21 CFR 892.1000	Same
Class	II	II	Same

ITEM	Proposed Device uMR 570	Predicate Device uMR 570 (K180925)	Remark
Indications For Use	The uMR 570 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 570 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	1.5 Tesla	1.5 Tesla	Same
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	width 700mm, height 530mm, length 1500mm	width 700mm, height 530mm, length 1500mm	Same
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	1.4ppm @ 50cm DSV 0.9ppm @ 45cm DSV 0.72ppm @ 40cm DSV 0.420ppm @ 30cm DSV 0.240ppm @ 20cm DSV 0.040ppm @ 10cm DSV	1.4ppm @ 50cm DSV 0.9ppm @ 45cm DSV 0.72ppm @ 40cm DSV 0.420ppm @ 30cm DSV 0.240ppm @ 20cm DSV 0.040ppm @ 10cm DSV	Same
Gradient system			

ITEM	Proposed Device uMR 570	Predicate Device uMR 570 (K180925)	Remark
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			
Resonant frequencies	63.87 MHz	63.87 MHz	Same
Number of transmit channels	1	1	Same
Number of receive channels	Up to 48	Up to 48	Same
Amplifier peak power per channel	20 kW	20 kW	Same
RF Coils			
Head & Neck Coil -16	Yes	Yes	Same
Body Array Coil - 6	Yes	Yes	Same
Body Array Coil - 12	Yes	Yes	Same
Breast Coil - 10	Yes	Yes	Same
Flex Coil Large - 4	Yes	Yes	Same
Flex Coil Small - 4	Yes	Yes	Same
Knee Coil - 12	Yes	Yes	Same
Lower Extremity Coil - 24	Yes	Yes	Same
Shoulder Coil - 12	Yes	Yes	Same
Small Loop Coil	Yes	Yes	Same
Spine Coil - 24	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
Cardiac Coil – 24	Yes	Yes	Same
Foot & Ankle Coil - 24	Yes	Yes	Same
Temporomandibular Joint Coil - 4	Yes	Yes	Same

ITEM	Proposed Device uMR 570	Predicate Device uMR 570 (K180925)	Remark
Head Coil - 24	Yes	No	The intended use is equivalent to previously cleared Head & Neck Coil -16 for head scan. More coil elements in the new coil allow better image quality and acceleration.
Head Coil - 12	Yes	No	The intended use is equivalent to previously cleared Head & Neck Coil -16 for head scan. More coil elements in the new coil allow better image quality and acceleration.
Carotid Coil - 8	Yes	No	The intended use is equivalent to previously cleared Flex Coil Small - 4 for neck scan. More coil elements in the new coil allow better image quality and acceleration.
Patient table			
Dimensions	width 640mm, height 880mm, length 2620mm	width 640mm, height 880mm, length 2620mm	Same
Maximum supported patient weight	250 kg	250 kg	Same
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

ITEM	Proposed Device uMR 570	Predicate Device uMR 570 (K180925)	Remark
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

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 570	Predicate Device uMR 570 (K180925)	Remark
Imaging Features			
lnline T1/T2*Map	Yes	No	Inline T1/T2*Map is significantly equivalent to single-echo/multi-echo gradient-echo imaging. Quantitative T1 and T2* maps are generated from variable flip angle and multi-echo images, respectively.
Phase Sensitive Inversion Recovery (PSIR)	Yes	No	PSIR is substantially equivalent to conventional inversion recovery (IR) and uses phase sensitive reconstruction 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.

8. Substantial Equivalence

The following testing was conducted on the proposed devices:

- Image Signal to Noise Ratio
- Image Uniformity
- Performance testing for Spectroscopy, Computed DWI
- Surface Heating of RF Receive
- 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 Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic
- Clinical performance evaluation
- Biocompatibility
- Performance testing for Inline T1/T2*Map
- Performance testing for SWI+
- Performance testing for Easy-scan

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 concludes that uMR 570 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.