May 18, 2023

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

Re: K230758
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: March 20, 2023
Received: March 20, 2023

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230758

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

March 20, 2023

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: 21 CFR 892.1000
Device Class: II

4. Identification of Predicate Devices(s)

Predicate Device
510(k) Number: K201540
Device Name: uMR 570
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH

Reference Device
510(k) Number: K222755
Device Name: uMR 680
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.

The modification performed on the uMR 570 (K201540) in this submission is due to the following changes that include:

(1) Addition and modification of pulse sequences
   a) New sequences: fse_dwi, grase, asl_3d, fse_mars_sle, gre_fine, gre_fq, gre_bssfp_ucs, svs_wfs, svs_stme.
   b) Added associated options for certain sequences: se_me (Add Inline T2 mapping), fse (Add QScan, Silicon-Only Image), fse_arms (Add QScan), fse_mx (Add QScan), fse_ssh (Add QScan, Silicon-Only Image), fse_wfi (Add QScan), se (Add QScan), epi_dwi (Add QScan, MultiBand), epi_bold (Add QScan, MultiBand), epi_dti (Add QScan, MultiBand), gre_swi (Add QScan), gre_fsp (Add QScan), gre_quick (Add QScan), gre (Add QScan), gre_fsp_c (Add Cardiac T2* mapping), gre_bssfp (Add Cardiac T1 mapping, Cardiac T2 mapping).
   c) Added additional accessory equipment required for certain sequences: gre_tof (Add respiratory, cardiac gating).

(2) Addition of MR imaging processing methods: Inline T2 mapping, Cardiac T1 mapping, Cardiac T2 mapping, Cardiac T2* mapping, Flow Quantification, Arterial Spin Labeling (3D ASL).

(3) Addition of Spectroscopy Sequences and Post Processing Features: SVS MRS (Liver), Prostate MRS, SVS MRS (Breast).

(4) Addition of New function: Implant mode, Remote Assistance.

(5) Addition of New Workflow Features: EasyScan.

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

6. Intended Use

The uMR 570 system system are 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 as below.

Table 1 Comparison of Hardware configuration

ITEM	Proposed Device uMR 570	Predicate Device uMR 570 (K201540)	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 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 (K201540)	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
Head Coil - 24	Yes	Yes	Same
Head Coil - 12	Yes	Yes	Same
Carotid Coil - 8	Yes	Yes	Same
Patient table			
Dimensions	width 640mm, height 880mm, length 2620mm	width 640mm, height 880mm, length 2620mm	Same

ITEM	Proposed Device uMR 570	Predicate Device uMR 570 (K201540)	Remark
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
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
Surface Heating	NEMA MS 14	ES 60601-1	Note 1

Note 1	The NEMA standards publication MS 14-2019 describes the procedure for heating RF coil heating under worst-case normal operating conditions. The results for the surface heating test showed that proposed devices perform as well as predicate devices.

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 (K201540)	Remark
Image Processing Features			
Inline T2 Mapping	Yes	No	Inline T2 Map is substantially equivalent to T2 Map processed by post-processing module. The map result displays inline without extra operation by post-processing module.
Arterial Spin Labeling (3D ASL)	Yes	No	3D ASL is substantially equivalent to FSE and uses extra arterial spin labeling preparation and imaging processing for cerebral blood flow (CBF) imaging without contrast agent.

Flow Quantification (FQ)	Yes	No	FQ is substantially equivalent to GRE and uses extra flow encoding and imaging processing for flow quantification.
Cardiac T1 Mapping	Yes	No	Cardiac T1 mapping is substantially equivalent to GRE and uses multiple TI acquisitions with IR preparation and imaging processing for cardiac T1 mapping.
Cardiac T2 Mapping	Yes	No	Cardiac T2 mapping is substantially equivalent to GRE and uses multiple T2-prep duration preparation acquisitions and imaging processing for cardiac T2 mapping.
Cardiac T2* Mapping	Yes	No	Cardiac T2* mapping is substantially equivalent to GRE and uses multiple TE acquisitions and imaging processing for cardiac T2* mapping.
Spectroscopy Features			
SVS MRS (Liver)	Yes	No	Liver spectroscopy is substantially equivalent to Spectroscopy and uses multi-echo acquisition and post-processing instead of single echo for fat quantification of liver.
Prostate MRS	Yes	No	Prostate spectroscopy is substantially equivalent to Spectroscopy and uses characteristic metabolites detection post processing for prostate spectroscopy.
SVS MRS (Breast)	Yes	No	Breast spectroscopy is substantially equivalent to Spectroscopy and uses characteristic metabolites detection post processing for breast spectroscopy.

Table 3 provides the new function and workflow features of the reference device in comparison to the predicate device.

Table 3 Comparison of the new function and workflow features

ITEM	**This Submission**	**Reference Device uMR 680 （K222755）**	**Remark**
Function			

Implant Mode	Yes	Yes	Same
Remote Assistance	Yes	Yes	Same
Workflow Features			
EasyScan	Yes	Yes	Same

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. Performance Data

The following testing was performed as described in the guidance/standards：

- MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

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

- Clinical performance evaluation
- Performance evaluation report for Flow Quantification,3D ASL, Inline T2 Mapping, Flow Quantification, Cardiac T1 Mapping, Cardiac T2 Mapping, Cardiac T2* Mapping, MARS+, MultiBand, QScan, Silicon-Only Imaging.
- Performance testing for Spectroscopy: Prostate MRS, SVS MRS (Breast), SVS MRS (Liver).
- System Validation report: Implant mode, Remote Assistance, EasyScan.

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 conclude 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.