April 10, 2024

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

Re: K240744
Trade/Device Name: uMR 680
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: March 18, 2024
Received: March 18, 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)*

K240744

Device Name

uMR 680

Indications for Use *(Describe)*

The uMR 680 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

1. Date of Prepared

March 18, 2024

2. Sponsor Identification

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3. Identification of Proposed Device(s)

Trade Name: uMR 680
Common Name: Magnetic Resonance Diagnostic Device
Model: uMR 680

Regulatory Information
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, MOS
Review Panel: Radiology

4. Identification of Predicate Devices(s)

Predicate Device
510(k) Number: K222755
Model: uMR 680
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Review Panel: Radiology

Reference Device
510(k) Number: K230152
Model: uMR Omega

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

5. Device Description

The uMR 680 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 680 Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

uMR 680 has been previously cleared by FDA via K222755. The modification performed on uMR 680 (K222755) in this submission is due to the addition of

- Breast Coil -24
- epi_se_mre
- MRE (Magnetic Resonance Elastography)

The modification does not affect the intended use or alter the fundamental scientific technology of the device.

6. Indications for Use

The uMR 680 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. 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 to Predicate Device

ITEM	Proposed Device uMR 680	Predicate Device uMR 680 (K222755)	Remark
Indications For Use	The uMR 680 system is indicated for use as a magnetic resonance	The uMR 680 system is indicated for use as a magnetic resonance	Same

ITEM	Proposed Device uMR 680	Predicate Device uMR 680 (K222755)	Remark
	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.	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.	
Breast Coil - 24	Yes	No	The intended use of Breast coil -24 is equivalent to previously cleared Breast Coil-10. The difference between them is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.

Table 2 Comparison to Reference Device

ITEM	Proposed Device uMR 680	Predicate Device uMR Omega (K230152)	Remark
MRE	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 conducted on uMR 680 and were provided in support of the substantial determination.

Item	Verification/Validation Method(s)	Acceptance Criteria	Summary of Results

Breast Coil - 24			
Surface heating	Perform test according to NEMA MS 14	The maximum temperature of all temperature probes shall not exceed 41℃.	Pass
General electrical/mechanical safety	Perform test according to ANSI/AAMI ES60601-1	Conform with ANSI/AAMI ES60601-1	Pass
SNR and Uniformity	Perform test according to NEMA MS 1, NEMA MS 3, NEMA MS 6 and NEMA MS 9	SNR and Uniformity shall fulfill with the design specification.	Pass
Biocompatibility	Biocompatibility evaluation in agreement with recommendations in Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"	Materials of construction and manufacturing materials exempt from testing according to the Biocompatibility guidance (Attachment G), the 510(k) numbers for devices where these materials have been previously approved, or full biocompatibility report (assessment of sensitization, irritation and cytotoxicity risks) for components that have direct contact with the patient.	All the materials of patient-contacting components for the Breast Coil - 24 are identical to uMR Omega which was cleared in K230152 in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).
EMC-immunity, electrostatic discharge	Perform test according to IEC 60601-1-2 and IEC 60601-4-2	Conform with IEC 60601-1-2 and IEC 60601-4-2	Pass
Clinical image quality	Evaluate the image generated by Breast Coil-24 with the same method as the predicate device	Image quality is sufficient for diagnostic use.	The U.S. Board Certified radiologist approves that image quality is sufficient for diagnostic use.
MRE/ epi_se_mre			
General electrical/mechanical safety	Perform test according to ANSI/AAMI ES60601-1	Conform with ANSI/AAMI ES60601-1	Pass
EMC	Perform test according to IEC 60601-1-2 and IEC 60601-4-2	Conform with IEC 60601-1-2 and IEC 60601-4-2	Pass
Performance	Perform a phantom and volunteer test under the proposed device with MRE	Bias of accuracy, repeatability, reproducibility and parameter sensitivity shall fulfill with the design specification.	Pass

Clinical image quality	Evaluate the image generated by MRE	Image quality is sufficient for diagnostic use.	The U.S. Board Certified radiologist approves that image quality is sufficient for diagnostic use.

The test results demonstrated that the device performed 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 680 Magnetic Resonance Diagnostic Device is substantially equivalent to the predicate device. It does not introduce new indications for use, and performance test results support that the technical characteristic change of the Breast Coil – 24 (i.e., the number of channels in the coil) and incorporating MRE/epi_se_mre do not introduce new potential hazards or safety risks.