



September 25, 2025

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

Re: K252371
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, QIH
Dated: July 30, 2025
Received: September 5, 2025

Dear Gao Xin:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

NINGZHI Digitally
LI-S signed by
NINGZHI LI-S

for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252371

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Please provide the device trade name(s).

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uMR 680

Please provide your Indications for Use below.

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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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

K252371

1. Date of Preparation

July 25, 2025

2. Sponsor Identification

Shanghai United Imaging Healthcare Co., Ltd.

No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Contact Person: Xin GAO

Position: Regulatory Affairs Specialist

Tel: +86-21-67076888-5386

Fax: +86-21-67076889

Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade Name: uMR 680

Common Name: Magnetic Resonance Imaging System

Model: uMR 680

Regulatory Information

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: II

Product Code: LNH

Secondary Product Code: MOS, QIH

Review Panel: Radiology

4. Identification of Primary/Reference Device(s)

Predicate Device

510(k) Number: K243397

Device Name: uMR 680

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: II

Product Code: LNH, MOS

Secondary Product Code: QIH

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.

This special 510(k) is to request modifications for the cleared uMR 680(K243397). The modifications performed on the uMR 680 in this submission are due to the following changes that include:

- (1) Addition of RF coils: Tx/Rx Head Coil.
- (2) Addition of a mobile configuration.

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

uMR 680 employs the same basic operating principles and fundamental technologies, and has the same indications for use as the predicate device. A comparison between the technological characteristics of proposed and predicate/reference devices is provided as below.

Table 1 Comparison of Indication for Use

ITEM	Proposed Device uMR 680	Predicate Device uMR 680 (K243397)	Remark
indications for use	The uMR 680 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse,	The uMR 680 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse,	Same

	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.	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.	
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Table 2 Comparison to Predicate device

ITEM	Proposed Device uMR 680	Predicate Device uMR 680(K243397)	Remark
General			
Magnet system			
Field Strength	1.5 Tesla	1.5 Tesla	Same
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	70cm	70cm	Same
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Gradient system			
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 96	Up to 96	Same
Amplifier peak power per channel	18 kW	18 kW	Same
RF Coils			
Tx/Rx Head Coil	Yes	No	Note 1
Mobile Configuration			
Mobile configuration	Yes	No	Note 2

Note 1	The intended use of Tx/Rx Head Coil is essentially identical to previously cleared Head Coil - 16. The difference is that the Tx/Rx Head Coil is of a 16 Legs High-Pass Birdcage used for transmitter coil. The difference did not raise new safety and effectiveness concerns.
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Note 2	The proposed device with mobile configuration has the same intended use and same basic technological characteristics than the predicate device system, with respect to the magnetic resonance features and functionalities. There are no differences in technical features compared to the predicate device, but minor modified hardware and an installation in a mobile trailer. The resulting differences have been tested and the conclusions from all verification and validation data suggest that the system bears an equivalent safety and performance profile to that of the predicate device and reference devices. The difference did not raise new safety and effectiveness concerns.
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8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of Results
Add RF coils: Tx/Rx Head Coil	● Biocompatibility ● EMC-immunity, electrostatic discharge ● SNR and Uniformity ● Surface Heating ● Clinical image quality ● General electrical/mechanical safety ● SAR	● 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". ● Perform test according to IEC 60601-1-2 and IEC 60601-4-2. ● Perform test according to NEMA MS 1, NEMA MS 3, NEMA MS 6 and NEMA MS 9. ● Perform test according to NEMA MS 14. ● Evaluate the image generated by RF coils: Tx/Rx Head Coil with the same method as the predicate device. ● Perform test according to ANSI/AAMI ES60601-1. ● Perform test according to IEC 60601-2-33 and NEMA MS 8.	● Materials of construction and manufacturing materials do not introduce chemicals that raise a biocompatibility concern. ● Conform with IEC 60601-1-2 and IEC 60601-4-2. ● SNR and Uniformity shall fulfill with the design specification. ● The maximum temperature of all temperature probes shall not exceed 41°C. ● Image quality is sufficient for diagnostic use. ● Conform with ANSI/AAMI ES60601-1. ● Conform with IEC 60601-2-33.	● Biocompatibility testing is not needed because device does not introduce a biocompatibility risk. ● Pass ● Pass ● Pass ● The U.S. Board Certified radiologist confirms that image quality is sufficient for diagnostic use. ● Pass ● Pass

Add mobile configuration	● EMC ● Clinical image quality ● General electrical/mechanical safety	● Perform test according to IEC 60601-1-2 and IEC 60601-4-2. ● Evaluate the image generated by RF coils: Tx/Rx Head Coil with the same method as the predicate device. ● Perform test according to ANSI/AAMI ES60601-1.	● Conform with IEC 60601-1-2 and IEC 60601-4-2. ● Image quality is sufficient for diagnostic use. ● Conform with ANSI/AAMI ES60601-1.	● Pass ● The U.S. Board Certified radiologist confirms that image quality is sufficient for diagnostic use. ● Pass
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Non-Clinical Testing

Non-clinical testing including surface heating, SAR and image performance tests were conducted for the uMR 680 to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device.

UNITED IMAGING HEALTHCARE claims conformance to the following standards and guidance:

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI/AAMIES60601-1: 2005/ (R) 2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012) [IncludingAmendment2(2021)] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-33 Ed. 4.0:2022 Medical Electrical Equipment - Part 2-33: Particular Requirements for The Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnostic
- IEC 60601-1-6:2010+A1:2013+A2:2020, Edition 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- NEMA MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 6-2008(R2014, R2020), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- NEMA MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- IEC /TS 60601-4-2: 2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software

- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Biocompatibility

- ISO 10993-5: 2009, Edition 3.0, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: 2021, Edition 4.0, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23: 2021, Edition 1.0, Biological evaluation of medical devices - Part 10: Tests for irritation.
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Other Standards and Guidance

- ISO 14971: 2019, Edition 3.0, Medical Devices – Application of risk management to medical devices
- Code of Federal Regulations, Title 21, Part 820 - Quality System Regulation
- Code of Federal Regulations, Title 21, Subchapter J - Radiological Health

Performance Verification

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

- Sample clinical images for Tx/Rx Head Coil were reviewed by U.S. board-certified radiologist comparing the proposed device and predicate device. It was shown that the proposed device can generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

9. Conclusion

Based on the comparison and analysis above, the proposed device has similar indications for use, performance, safety equivalence, and effectiveness 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. The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.