



July 16, 2025

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

Re: K243397
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: June 20, 2025
Received: June 20, 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
Li -S

Digitally
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

510(k) Number (if known)

K243397

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.

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510(k) SUMMARY

1. Sponsor Identification

Shanghai United Imaging Healthcare Co., Ltd.

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2. 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, MOS

Secondary Product Code: QIH

Review Panel: Radiology

3. Identification of Primary/Reference Device(s)

Predicate Device

510(k) Number: K240744

Device Name: uMR 680

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: II

Product Code: LNH, MOS

Review Panel: Radiology

Reference Device#1

510(k) Number: K220332

Device Name: uWS-MR

Regulation Name: Medical Image Management and Processing System

Regulatory Class: II

Product Code: LLZ, QIH

Review Panel: Radiology

Reference Device#2

510(k) Number: K234154

Device Name: uPMR 790

Regulation Name: Emission computed tomography system

Regulatory Class: II

Product Code: OUO, MOS

Review Panel: Radiology

Reference Device#3

510(k) Number: K230152

Device Name: uMR Omega

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: II

Product Code: LNH, MOS

Review Panel: Radiology

4. 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 traditional 510(k) is to request modifications for the cleared uMR 680(K240744). The modifications performed on the uMR 680 in this submission are due to the following changes that include:

- (1) Addition of RF coils and corresponding accessories: Breast Coil -12, Biopsy Configuration, Head Coil-16, Positioning Couch-top, Coil Support.
- (2) Deletion of VSM (Wireless UIH Gating Unit REF 453564324621, ECG module Ref 989803163121, SpO2 module Ref 989803163111).
- (3) Modification of the dimensions of Detachable table: from width 826mm, height 880mm, 2578mm to width 810mm, height 880mm, length 2505mm.
- (4) Addition and modification of pulse sequences
 - a) New sequences: gre_snap, gre_quick_4dncemra, gre_pass, gre_mtp, gre_trass, epi_dwi_msh, epi_dti_msh, sv_hise.
 - b) Added associated options for certain sequences: fse(add Silicone-Only Imaging, MicroView, MTC, MultiBand), fse_arms(add Silicone-Only Imaging), fse_ssh(add Silicone-Only Imaging), fse_mx(add CEST, T1rho, MicroView, MTC), fse_arms_dwi(add MultiBand), asl_3d(add multi-PLD), gre(add T1rho, MTC, output phase image), gre_fsp(add FSP+), gre_bssfp(add CASS, TI Scout), gre_fsp_c(add 3D LGE, DB/GB PSIR), gre_bssfp_ucs(add real time cine), gre_fq(add 4D Flow), epi_dwi(add IVIM), epi_dti(add DKI, DSI).
 - c) Added additional accessory equipment required for certain sequences: gre_bssfp(add Virtual ECG Trigger).
 - d) Name change of certain sequences: gre_fine(old name: gre_bssfp_fi).
 - e) Added applicable body parts: gre_ute, gre_fine, fse_mx.
- (5) Addition of imaging reconstruction methods: AI-assisted Compressed Sensing (ACS), Spark artifact Correction (SparkCo).
- (6) Addition of imaging processing methods: Inline Cardiac Function, Inline ECV, Inline MRS, Inline MOCO, 4D Flow, SNAP, CEST, T1rho, FSP+, CASS, PASS, MTP.
- (7) Addition of workflow features: TI Scout, EasyCrop, ImageGuard, Mocap, EasyFACT, Auto Bolus tracker, Breast Biopsy and uVision.
- (8) Modification of workflow features: EasyScan(add applicable body parts)

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

5. 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.

6. 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 to Predicate device

ITEM	Proposed Device uMR 680	Predicate Device uMR 680(K240744)	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
Magnet Homogeneity	1.40ppm @ 50cm DSV 0.90ppm @ 45cm DSV 0.45ppm @ 40cm DSV 0.190ppm @ 30cm DSV 0.120ppm @ 20cm DSV 0.040ppm @ 10cm DSV	1.40ppm @ 50cm DSV 0.90ppm @ 45cm DSV 0.45ppm @ 40cm DSV 0.190ppm @ 30cm DSV 0.120ppm @ 20cm DSV 0.040ppm @ 10cm DSV	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			
Head & Neck Coil -24	Yes	Yes	Same
Spine Coil - 32	Yes	Yes	Same
Body Array Coil - 12	Yes	Yes	Same

ITEM	Proposed Device uMR 680	Predicate Device uMR 680(K240744)	Remark
Body Array Coil - 24	Yes	Yes	Same
Breast Coil - 10	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
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
Carotid Coil - 8	Yes	Yes	Same
Flex Coil Large - 8	Yes	Yes	Same
Flex Coil Small - 8	Yes	Yes	Same
Infant Coil-24	Yes	Yes	Same
SuperFlex Large - 12	Yes	Yes	Same
SuperFlex Small - 12	Yes	Yes	Same
SuperFlex Body - 24	Yes	Yes	Same
Breast Coil-24	Yes	Yes	Same
Breast Coil 12	Yes	No	Note 1
Head Coil 16	Yes	No	Note 2
Patient table			
Dimensions	Patient Table: width 640 mm, height 880 mm, length 2620 mm	Patient Table: width 640 mm, height 880 mm, length 2620 mm	Same
	Detachable Table: width 826 mm, height 880 mm, length 2578 mm	Detachable Table: width 810 mm, height 880 mm, length 2505 mm	Note 3
Maximum supported patient weight	Patient Table: 250 kg	Patient Table: 250 kg	Same
	Detachable Table: 310 kg	Detachable Table: 310 kg	Same
Accessories			
Vital Signal Gating	/	Wireless UIH Gating Unit REF 453564324621 ECG module Ref 989803163121 SpO2 module Ref 989803163111(alternative)	Note 4

ITEM	Proposed Device uMR 680	Predicate Device uMR 680(K240744)	Remark
	uVWMERP uMVRX (alternative)	uVWMERP uMVRX (alternative)	Same
	mmw100 (optional)	mmw100 (optional)	Same
Image Processing			
Inline ECV	Yes	No	Note 5
Inline MOCO	Yes	No	Note 6
MTP	Yes	No	Note 7
Workflow			
TI Scout	Yes	No	Note 8
Breast Biopsy	Yes	No	Note 9
Auto Bolus tracker	Yes	No	Note 10
EasyScan	Yes	Yes	Note 11
Image Reconstruction			
SparkCo	Yes	No	Note 12

Table 2 Comparison to Reference device#1

ITEM	Proposed Device uMR 680	Reference Device#1 uWS-MR (K220332)	Remark
Image Processing			
Inline Cardiac function	Yes	Yes	Note 13
Inline MRS	Yes	Yes	Note 14

Table 3 Comparison to Reference device#2

ITEM	Proposed Device uMR 680	Reference Device#2 uPMR 790 (K234154)	Remark
Workflow			
EasyCrop	Yes	Yes	Note 15
ImageGuard	Yes	Yes	Same
Mocap (also named MoCap-Monitoring)	Yes	Yes	Same
EasyFACT (also named Inline FACT)	Yes	Yes	Same
Image Processing			
4D Flow	Yes	Yes	Same
SNAP	Yes	Yes	Same
CEST	Yes	Yes	Same
T1rho	Yes	Yes	Same
FSP+	Yes	Yes	Same
CASS	Yes	Yes	Same
PASS	Yes	Yes	Same

Table 4 Comparison to Reference device#3

ITEM	Proposed Device uMR 680	Reference Device#3 uMR Omega (K230152)	Remark
ACS	Yes	Yes	Same
uVision	Yes	Yes	Note 16

Note 1	The intended use of Breast Coil - 12 is essentially identical to previously cleared Breast Coil - 10. There are two differences between Breast Coil - 12 and Breast Coil - 10. One is that Breast Coil - 12 can be used with Biopsy Configuration to provide breast biopsy function. The other one is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.
Note 2	The intended use of Head Coil - 16 is equivalent to Head Coil - 12 previously cleared via K200024. The only difference between them is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.
Note 3	The dimensions of detachable table were changed from width 826mm, height 880mm, length 2578mm to width 810mm, height 880mm, length 2505mm. The difference did not raise new safety and effectiveness concerns.
Note 4	One alternative wireless VSM was removed from the proposed device. The difference did not raise new safety and effectiveness concerns.
Note 5	Inline ECV aims to calculate the pixel-wise ECV (extracellular volume fraction) images from the native and post T1 mapping. The difference did not raise new safety and effectiveness concerns.
Note 6	Inline MOCO is a function that perform motion correction on MR images, which can reduce the motion caused by physiological factors such as breathing and heart beat in the images. The difference did not raise new safety and effectiveness concerns.
Note 7	MTP is substantially equivalent to GRE and acquires two flip angles and multi-echo images with one scan, and then uses specific image processing to attain multi-parametric images. The difference did not raise new safety and effectiveness concerns.
Note 8	TI Scout automatically selects the TI frame which has the darkest ventricular myocardium of the TI Scout image, allowing users to achieve the best inversion time (TI) and simplifying the workflow which needed the TI. The difference did not raise new safety and effectiveness concerns.
Note 9	Breast Biopsy is a workflow that can provide biopsy instruction for technicians based on the hardware and lesion parameters, the instruction include the biopsy grid coordinate, needle block cell and needle depth. The difference did not raise new safety and effectiveness concerns.
Note 10	Auto Bolus tracker is a feature that automatically recognizes the time when the contrast agent reaches the target position and triggers the scan. The difference did not raise new safety and effectiveness concerns.
Note 11	EasyScan of the proposed device supports more body parts than that of the predicate device. In this submission, breast and pelvis and hip and ankle and thorax are included. The difference did not raise new safety and effectiveness concerns.
Note 12	SparkCo is an algorithm that can detect and correct spark artifacts (a specific occurring MRI artifact that is caused by electromagnetic interference (EMI)) in MRI images. The difference did not raise new safety and effectiveness concerns.

Note 13	During this submission, inline ED/ES Phases Recognition was included in Inline Cardiac function, which allows automatically rearrange the cardiac images into an aligned cardiac cycle. The difference did not raise new safety and effectiveness concerns.
Note 14	Inline MRS of the proposed device are the same as the predicate device. The difference is that the algorithms of Inline MRS are shifted from the post-processing workstation to inline console. The difference did not raise new safety and effectiveness concerns.
Note 15	EasyCrop of the proposed device supports more body parts than that of the predicate device. In this submission, head and carotid and renal are included. The difference did not raise new safety and effectiveness concerns.
Note 16	uVision of the reference device just supports Hand Gesture Recognition. During this submission, Body Part Recognition function was included in uVision, which allows assist patient positioning by performing image recognition on human natural images through a 3D camera during the positioning stage. The difference did not raise new safety and effectiveness concerns.

7. Performance Data

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

Non-Clinical Testing

Non-clinical testing including surface heating 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) [Including Amendment2(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 60825-1: 2014, Edition 3.0, Safety of laser products - Part 1: Equipment classification and requirements.

- 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.
- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- IEC 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.
- NEMA MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2-2008(R2020), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 4-2023, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- NEMA MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- 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 8-2016, Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- 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 /TR 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

- NEMA PS 3.1-3.20(2022d): Digital Imaging and Communications in Medicine (DICOM)
- 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.

- Performance evaluation report for AI-assisted Compressed Sensing(ACS), TI Scout, EasyScan, EasyCrop, ImageGuard, Mocap, Breast Biopsy, EasyFACT, Auto Bolus tracker, Inline Cardiac, Inline ECV, Inline MOCO, Silicon-Only Imaging, Brain MRS using SVS-HISE, 4D Flow, CEST, T1rho, MTP, SparkCo and uVision.
- Sample clinical images for all clinical sequences, coils and imaging processing 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.

Summary of the Machine Learning Algorithm

● ***AI-assisted Compressed Sensing(ACS)***

ACS (AI-assisted Compressed Sensing) is an acceleration reconstruction technique. By adding one more regularization term from AI module, ACS is a slight extension of CS (Compressed Sensing).

The training dataset of AI module in ACS was collected from a variety of anatomies, image contrasts, and acceleration factors. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulted in a total of 1,262,912 samples. Fully-sampled k-space data were collected and transformed to image space as the ground-truth. The input data were generated by sub-sampling the fully-sampled k-space data with different parallel imaging acceleration factors and partial Fourier factors. All data were manually quality controlled before included for training.

ACS has already received FDA cleared for the uMR Omega system, with the approval number K243122. In addition, we have conducted additional validation on the uMR 680 system with 1724 samples from 35 volunteers, with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups (Table 5).

Table 5 Distribution of volunteer dataset

Subjects' Characteristics (N=35)	N(%)
Gender, N(%)	
Male	23(65.7%)
Female	12(34.3%)
Age, N(%) : Min=18, Max=68, Avg.=34.2, Std.=10.83	
18-29	4(11.4%)
30-44	12(34.3%)
45-64	10(28.6%)
>=65	9(25.7%)
Ethnicity, N(%)	
White	9(25.7%)
Asian	21(60%)
Black	5(14.3%)
Body Mass Index (BMI), N(%) : Min=16.0, Max=53.5, Avg.=23.3, Std.=9.57	
Underweight (<18.5)	6(17.1%)
Healthy weight (18.5-24.9)	14(40%)
Overweight (25.0-29.9)	10(28.6%)
Obesity (>=30.0)	5(14.3%)

The independence of these testing datasets were ensured by collecting testing data from various clinical sites and during separated time periods and on subjects different from the training data. Thus, the testing data have no overlap with the training data and are completely independent. No clinical subgroups and confounders have been defined for the datasets. The acceptance criteria for performance testing and the corresponding testing results can be found in Table 6.

Table 6 The performance evaluation report criteria of ACS

Evaluation Item	Evaluation Method	Criteria	Results
AI Module Verification Test	The performance of AI was evaluated by comparing the input error and output error with respect of NRMSE. If the NRMSE of the AI output is less than the NRMSE of input, the	The ratio of error: NRMSE(output)/NRMSE(input) is always less than 1.	Pass

	performance of AI is considered to be validated.		
Image SNR	Calculating SNR for both ACS and CS images under the same acceleration factors and protocol parameters	ACS has higher SNR than CS.	Pass
Image Resolution	Calculating the resolution value in elliptic ROI using the (standard deviation (SD) / mean value(S)) for both ACS and CS images under the same acceleration factors and protocol parameters	ACS has higher (standard deviation (SD) / mean value(S)) values than CS.	Pass
Image Contrast	Comparing the ROI signal intensities between images acquired with fully sampled and ACS images under the same acceleration factors with different TI values	Bland-Altman analysis of image intensities acquired using fully sampled and ACS was shown with less than 1% bias and all sample points falls in the 95% confidence interval.	Pass
Image Uniformity	Images of the phantom were acquired with fully sampled and ACS protocol respectively. Method used here for data analysis is according to NEMA MS 6-2008(R2004)	ACS achieved significantly same image uniformities as fully sampled image	Pass
Structure Measurement	Dimensions of selected small structures were identified and measured on ACS images as well as on fully sampled images.	Measurements differences on ACS and fully sampled images of same structures under 5% is acceptable.	Pass

The ACS was shown to perform better than CS by measuring SNR and resolution using images from various ethnicities, age groups, BMIs, and pathological variations. Meanwhile, results from the tests also demonstrated that ACS maintained image qualities, such as contrast and uniformity, as compared against fully sampled data as golden standards, thus ACS introduces significantly few risks of image quality degradation and artifacts.

In addition, ACS images were evaluated by American Board of Radiologists certificated physicians, covering a range of protocols and body parts. Clinical

protocols various contrast such as T1, T2, T1Flair, T2Flair, PD, STIR, etc. The evaluation reports from radiologists verified that ACS meets the requirements of clinical diagnosis. All ACS images were rated with equivalent or higher scores in terms of diagnosis quality.

● **SparkCo**

SparkCo (Spark artifact Correction) is an algorithm that can detect and correct spark artifacts in MRI images, which will help to restore spark-free image for clinical review when encountering spark artifacts on MRI images.

The spark detection module of SparkCo is based on the AI algorithm, however, it won't change the image directly, and it only provides the K-space location of spark points. Then, the spark correction module based on traditional parallel imaging reconstruction algorithm will utilize the spark detection results to remove spark points and restore the full-sampled K-space. Through this two-step process, SparkCo can correct spark artifacts and restore the spark-free image.

The training dataset for the AI module in SparkCo was generated by simulating spark artifacts from spark-free raw data. The spark-free raw data comprises 61 cases collected from 10 volunteers across various body parts and MRI sequences. From this data, a total of 24,866 spark slices, along with the corresponding ground truth (i.e., the location of spark points), were generated for training. Additionally, 159 spark slices were generated as the simulated spark testing dataset.

The real-world spark raw data consists of 59 cases collected from 15 patients, serving as the independent testing dataset, which does not overlap with the training dataset.

The demographic distribution of this testing dataset is presented in Table 4. And this testing dataset were acquired by using uMR 1.5T and uMR 3T scanners, which cover representative protocols in clinical practice such as T1, T2, and PD with and without fat saturation. Details of acquisition from various body parts are outlined in Table 7.

Table 7 The demographic distribution of real-world spark testing dataset

Subjects' Characteristics (N=15)	N(%)
Gender, N(%)	
Male	9(60%)
Female	6(40%)
Age, N(%) : Min=18, Max=59, Avg.=30.8, Std.=9.88	
18-29	2(20%)
30-44	8(53.3%)
45-64	4(26.7%)
>=65	0(0.0%)
Ethnicity, N(%)	
White	N.A.

Asian	15(100%)
Body Mass Index (BMI), N(%): Min=17.0, Max=53.5, Avg.=24.0, Std.=7.05	
Underweight (<18.5)	2(13.3%)
Healthy weight (18.5-24.9)	10(66.7%)
Overweight (25.0-29.9)	3(20%)
Obesity (>=30.0)	0(0.0%)

Remark: The performance of SparkCo is irrelevant with human ethnicity. The spark detection module of SparkCo is designed to classify and locate the spark signals with abnormally high amplitude in the K-space data. These spark signals exhibit similar characteristics across different human ethnicity, so no testing was conducted on other human ethnicity.

Table 8 The various body parts and number of cases included in the real-world spark testing dataset

Body Parts	Number of cases
Head	21
C-spine	5
Shoulder	1
Wrist	1
Thorax	2
Abdomen	8
L-spine	2
Pelvis	19
Total	59

By the test, the SparkCo have been demonstrated with high spark detection accuracy and spark correction effectiveness, as the following Table 9 shows.

Table 9 The test methods and test results of SparkCo

Test parts	Test Methods	Accept criteria	Test Results
Test on the spark detection accuracy	Based on the real-world testing dataset, calculating the detection accuracy by comparing the spark detection results with the ground-truth.	The average detection accuracy need be larger than 90%	The average detection accuracy is 94%.
Test on the spark correction performance	Based on the simulated spark testing dataset, calculating the PSNR (Peak signal-to-noise ratio) of the spark-corrected images and original spark images	The average PSNR of spark-corrected images need to be higher than the spark images. Spark artifacts need to be reduced or corrected	The average PSNR of spark-corrected images is 1.6 higher than the spark images. The images with spark artifacts were

	Based on the real-world spark dataset, evaluating the image quality improvement between the spark-corrected images and spark images by one experienced evaluator.	after enable the SparkCo.	successfully corrected after enable the SparkCo.
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● **Inline ED/ES Phases Recognition**

The performance testing for inline ED/ES phases recognition algorithm was performed on 95 cases.

The validation type and acceptance criteria is shown in Table 10 below:

Table 10 Validation type and acceptance criteria

Validation Type	Acceptance Criteria
The error between the phase indices calculated by the algorithm for the ED and ES of test data and the gold standard phase indices.	The average error does not exceed 1 frame.

The distribution and protocols for volunteer dataset used for validation is listed in Table 11. A total of 95 cases from 56 volunteers were used.

Table 11 Distribution of volunteer dataset

Gender	Number of people	Number of cases
Male	36	72
Female	10	13
Unknown	10	10
Age		
[20,30)	15	20
[30,40)	9	23
[40,50)	14	22
[50,60)	5	17
>=60	3	3
Unknown	10	10
Field strength		
1.5T	10	19
3.0T	36	66
Unknown	10	10
Disease conditions		
NOR	46	85
MINF	2	2
DCM	2	2
HCM	5	5

ARV	1	1
Ethnicity		
Asian	22	60
White	16	16
Black	8	9
Unknown	10	10

The error between the frame indexes calculated by the algorithm for the ED and ES of all test data and the gold standard frame index is 0.13 frames, which does not exceed 1 frame. Meanwhile, the subgroup analysis shows that the proposed algorithm has good generalization in different subgroups.

Table 12 Subgroup analysis of results

Gender	Case Number	Average of frame index differences
Male	72	0.12
Female	13	0.14
Unknown	10	0.14
Age		
[20,30)	20	0.13
[30,40)	23	0.10
[40,50)	22	0.16
[50,60)	17	0.10
>=60	3	0.16
Unknown	10	0.14
Field strength		
1.5T	19	0.13
3.0T	66	0.12
Unknown	10	0.14
Disease conditions		
NOR	85	0.12
MINF	2	0.15
DCM	2	0.13
HCM	5	0.15
ARV	1	0.14
Ethnicity		
Asian	60	0.11
White	16	0.19
Black	9	0.13
Unknown	10	0.14

The training data used for the training of the inline ED/ES phases recognition algorithm is independent of the data used to test the algorithm.

● **Inline ECV**

A total of 90 images from 28 patients were used as the test data. For each patient, it had the native t1map data and post t1map data.

The validation type and acceptance criteria is shown in the Table 12 below:

Table 23 Validation type and acceptance criteria

Validation Type	Acceptance Criteria
Passing rate	To verify the effectiveness of the algorithm, the subjective evaluation method was used. The segmentation result of each case was obtained with the algorithm, and the segmentation mask was evaluated with the following criteria. The test pass criteria was: no failure cases, satisfaction rate $S/(S+A+F)$ exceeding 95%. The criteria is as follows: • Satisfied (S): the segmentation myocardial boundary adheres to the myocardial boundary and blood pool ROI is within the blood pool excluding the papillary muscles. • Acceptable (A): These are small missing or redundant areas in the myocardial segmentation but not obviously and the blood pool ROI is within the blood pool excluding the papillary muscles. • Fail (F): The myocardial mask does not adhere to the myocardial boundary or the blood pool ROI is not within the blood pool, or the blood pool ROI contains papillary muscles.

A total of 90 images from 28 patients were used as the test data. For each patient, it had the native t1map data and post t1map data. The distribution is as the following table 14.

Table 14 Distribution of Patient dataset

Gender	Number
Male	20
Female	8
Age	
<18	1
18-28	4
29-40	1
> 41	22
Protocol	
post_t1map_sax	28
native_t1map_sax	28
BMI (kg/m(2))	
<18.5	0
[18.5, 25)	7
>=25	15
Unknown	6

Magnetic field strength (T)	
1.5	13
3	15
Ethnicity	
Asian	17
White	11
Healthy	
Negative	19
Postive	4
Unknown	5

According to the subgroup analysis in Table 15, it can be seen that the segmentation algorithm performs as expected in different subgroups.

Table 15 Segmentation algorithm subgroup analysis

Gender	Satisfied (S)	Acceptable (A)	Total Failure Rate	Total satisfaction Rate
Male	100%	0%	0%	100%
Female	100%	0%	0%	100%
Age				
18-28	100%	0%	0%	100%
29-40	100%	0%	0%	100%
> 41	100%	0%	0%	100%
Protocol				
post_t1map_sax	100%	0%	0%	100%
native_t1map_sax	100%	0%	0%	100%
BMI (kg/m(2))				
<18.5	100%	0%	0%	100%
[18.5, 25)	100%	0%	0%	100%
>=25	100%	0%	0%	100%
Unknown	100%	0%	0%	100%
Magnetic field strength (T)				
1.5	100%	0%	0%	100%
3	100%	0%	0%	100%
Ethnicity				
Asian	100%	0%	0%	100%
White	100%	0%	0%	100%
Healthy				
Negative	100%	0%	0%	100%
Postive	100%	0%	0%	100%
Unknown	100%	0%	0%	100%

The training data used for the training of the cardiac ventricular segmentation algorithm is independent of the data used to test the algorithm.

● **Inline MOCO**

The performance testing for inline MOCO algorithm was performed on 287 cases during the product development, where 105 cases were cardiac perfusion images (data shown in Table 3) and 182 cases were cardiac dark blood images.

The validation type and acceptance criteria is shown in the Table 16 below:

Table 16 Validation type and acceptance criteria

Validation Type	Acceptance Criteria
Dice	The average Dice coefficient of the left ventricular myocardium after motion correction is greater than 0.87.

Testing Data Information

1) Cardiac Perfusion Images Subgroup Information

Sample Size:

Table 17 Sample size information of testing data

Dataset	Patients Number	Cases Number
Testing Data	60	105

(Note: One patient may have multiple cases, because of the differences in slice location.)

Equipment and Protocols:

The data were acquired from 1.5T and 3T magnetic resonance imaging equipment from UIH. The data were GRE sequence data, including T1 contrast, with the scanning range covering the cardiac.

Clinical Subgroups:

The subgroup information of cardiac perfusion images in testing data is summarized below.

Table 18 Cardiac perfusion images subgroup information

Subgroup	Details of each subgroup	Number of cases
Age	<22	3
	[22, 40)	17
	[40, 60)	38
	[60, 90)	47
Gender	Female	26
	Male	79
Ethnicity	Asian	74
	White	31
BMI (kg/m(2))	< 18.5	1
	[18.5, 25)	23

	>=25	37
	Unknown	44
Magnetic field strength (T)	1.5	40
	3.0	65
Disease conditions	Positive	49
	Negative	16
	Unknown	40

2) Cardiac Dark Blood Images Subgroup Information

Sample Size:

Table 19 Sample size information of testing data

Dataset	Patients Number	Cases Number
Testing Data	33	182

(Note: One patient may have multiple cases, because of the differences in slice location.)

Equipment and Protocols:

The data were acquired from 1.5T and 3T magnetic resonance imaging equipment from UIH. The data were FSE sequence data, including T2 contrast, with the scanning range covering the cardiac.

Clinical Subgroups:

The subgroup information of cardiac dark blood images in testing data is summarized below.

Table 20 Cardiac dark blood images subgroup information

Subgroup	Details of each subgroup	Samples Number
Age	<22	34
	[22, 40)	110
	[40, 60)	34
	[60, 90)	4
Gender	Female	58
	Male	124
Ethnicity	Asian	89
	White	64
	Black	26
	Hispanic	3
BMI (kg/m(2))	< 18.5	21
	[18.5, 25)	79
	>=25	76
	Unknown	6
Magnetic field strength (T)	1.5	50
	3.0	132
Disease conditions	Positive	3

	Negative	35
	Unknown	144

Performance Testing Summary

1) Cardiac Perfusion Images Performance Testing Summary

The average Dice coefficient of the left ventricular myocardium after motion correction is 0.92, which is greater than 0.87. Meanwhile, the subgroup analysis shows that (Table 6) the proposed device algorithm has good generalization in different subgroups.

Table 21 Cardiac perfusion images subgroup performance test

Age	Average Dice after motion correction
<22	0.92
[22, 40)	0.93
[40, 60)	0.92
[60, 90)	0.92
Gender	Average Dice after motion correction
Female	0.92
Male	0.92
Ethnicity	Average Dice after motion correction
Asian	0.92
White	0.91
BMI (kg/m(2))	Average Dice after motion correction
< 18.5	0.95
[18.5, 25)	0.93
>=25	0.91
Unknown	0.93
Magnetic field strength (T)	Average Dice after motion correction
1.5	0.92
3.0	0.93
Disease conditions	Average Dice after motion correction
Positive	0.93
Negative	0.92
Unknown	0.91

2) Cardiac Dark Blood Images Performance Testing Summary

The average Dice coefficient of the left ventricular myocardium after motion correction is 0.96, which is greater than 0.87. Meanwhile, the subgroup analysis shows that (Table 7) the proposed device algorithm has good generalization in different subgroups.

Table 22 Cardiac dark blood images subgroup performance test

Age	Average Dice after motion correction
<22	0.96
[22, 40)	0.96
[40, 60)	0.96
[60, 90)	0.95
Gender	Average Dice after motion correction
Female	0.96
Male	0.96
Ethnicity	Average Dice after motion correction
Asian	0.96
White	0.95
Black	0.95
Hispanic	0.96
BMI (kg/m(2))	Average Dice after motion correction
< 18.5	0.96
[18.5, 25)	0.96
>=25	0.96
Unknown	0.98
Magnetic field strength (T)	Average Dice after motion correction
1.5	0.96
3.0	0.96
Disease conditions	Average Dice after motion correction
Positive	0.97
Negative	0.96
Unknown	0.96

Standard Annotation Process

For ground truth annotations, all ground truth was annotated by a well-trained annotator. The annotator used an interactive tool to observe the image, and then labeled the left ventricular myocardium in the image. Finally, all ground truth was evaluated by three licensed physicians with U.S. credentials.

Testing & Training Data Independence

The training data used for the training of the inline MOCO algorithm is independent of the data used to test the algorithm.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uMR 680 was found to have a safety and effectiveness profile that is similar to the predicate device.

8. 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.