



July 17, 2025

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

Re: K243547
Trade/Device Name: uMR Ultra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: June 26, 2025
Received: June 26, 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

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

Indications for Use

Submission Number (if known)

K243547

Device Name

uMR Ultra

Indications for Use (Describe)

The uMR Ultra 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. Date of Preparation

K243547

November 12, 2024

2. Sponsor Identification

Shanghai United Imaging Healthcare Co.,Ltd.

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Contact Person: Xin GAO

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3. Identification of Proposed Device

Trade Name: uMR Ultra

Common Name: Magnetic Resonance Imaging System

Model: uMR Ultra

Regulatory Information

Regulation Number: 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: LNH

Review Panel: Radiology

4. Identification of Primary/Reference Device(s)

Predicate Device

510(k) Number: K243122

Device Name: uMR Omega

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: LNH

Review Panel: Radiology

Reference device#1

510(k) Number: K220332

Device Name: uWS-MR

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: 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

Review Panel: Radiology

5. Device Description

uMR Ultra is a 3T superconducting magnetic resonance diagnostic device with a 70cm size patient bore and 2 channel RF transmit system. 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. uMR Ultra is designed to conform to NEMA and DICOM standards.

A detailed comparison between the new and modified features included in the subject device and predicate device refers to Section 7.

6. Indications for Use

The uMR Ultra 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 of Indication for Use to Predicate device

ITEM	Proposed Device uMR Ultra	Predicate Device uMR Omega (K243122)	Remark
indications for use	The uMR Ultra 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 Omega 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

Table 2 Comparison to Predicate device

ITEM	Proposed Device uMR Ultra	Predicate Device uMR Omega	Remark
General			
Magnet system			
Field Strength	3.0 Tesla	3.0 Tesla	Same
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	70 cm	75 cm	Note 1
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	≤ 2.30 ppm @ 50cm DSV ≤ 0.80 ppm @ 45cm DSV ≤ 0.38 ppm @ 40cm DSV ≤ 0.08 ppm @ 30cm DSV ≤ 0.02 ppm @ 20cm DSV ≤ 0.002 ppm @ 10cm DSV	≤ 2.30 ppm @ 50cm DSV ≤ 0.80 ppm @ 45cm DSV ≤ 0.38 ppm @ 40cm DSV ≤ 0.08 ppm @ 30cm DSV ≤ 0.02 ppm @ 20cm DSV ≤ 0.002 ppm @ 10cm DSV	Same

ITEM	Proposed Device uMR Ultra	Predicate Device uMR Omega	Remark
Gradient system			
Max gradient amplitude	100 mT/m	45 mT/m	Note 2
Max slew rate	200 T/m/s	200 T/m/s	Same
Shielding	active	active	Same
Cooling	water	water	Same
RF system			
Resonant frequencies	128.23 MHz	128.23 MHz	Same
Number of transmit channels	2	2	Same
Amplifier peak power per channel	Option 1: 20 kW	Option 1: 18 kW Option 2: 20 kW	Note 3
Maximum number of receive channels	192	96	Note 4
RF Coils			
Volume Transmit Coil	Yes	Yes	Same
Breast Coil - 12	Yes	Yes	Same
Breast Coil - 24	Yes	Yes	Same
SuperFlex Large - 12	Yes	Yes	Same
UHD SuperFlex Large - 24	Yes	No	Note 5
SuperFlex Small - 12	Yes	Yes	Same
UHD SuperFlex Small - 24	Yes	No	Note 6
SuperFlex Body - 24	Yes	Yes	Same
SuperFlex Whole Body - 48	Yes	No	Note 7
Head Coil - 16	Yes	Yes	Same
Head & Neck Coil - 24	Yes	Yes	Same
Head & Neck Coil - 48	Yes	Yes	Same
UHD SuperFlex Free - 24	Yes	No	Note 8
Infant Coil - 24	Yes	Yes	Same

ITEM	Proposed Device uMR Ultra	Predicate Device uMR Omega	Remark
Small Loop Coil	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
Wrist Coil - 24	Yes	No	Note 9
Tx/Rx Head Coil	Yes	Yes	Same
Shoulder Coil - 12	Yes	Yes	Same
Shoulder Coil - 24	Yes	No	Note 10
Spine Coil - 48	Yes	Yes	Same
Tx/Rx Knee Coil - 24	Yes	Yes	Same
Foot & Ankle Coil - 24	Yes	Yes	Same
Carotid Coil - 8	Yes	Yes	Same
Temporomandibular Joint Coil - 4	Yes	Yes	Same
Patient table			
Maximum supported patient weight	310 kg	310 kg	Same
Accessories			
Vital Signal Gating	ECG, Respiration and pulse module	ECG, Respiration and pulse module	Same
Tilt Support	Yes	No	Note 11
Positioning Couch-top	Yes	No	Note 12
Coil Support	Yes	No	Note 13
Patient Bore Projector	Yes	No	Note 14
uVision			
Body Part Recognition	Yes	No	Note 15

ITEM	Proposed Device uMR Ultra	Predicate Device uMR Omega	Remark
Hand Gesture Recognition	Yes	Yes	Same
Safety			
Electrical Safety	Comply with ES 60601-1	Comply with ES 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	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	Comply with ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-5 and ISO 10993-10	Same
Surface Heating	NEMA MS 14	NEMA MS 14	Same
Imaging Features			
4D CEMRA	Yes	Yes	Same
4D NCEMRA	Yes	Yes	Same
ARMS	Yes	Yes	Same
ARMS DWI	Yes	Yes	Same
3D ASL	Yes	Yes	Same
Multi-PLD ASL	Yes	Yes	Same
bFAST	Yes	Yes	Same
BOLD	Yes	Yes	Same
Brain Perfusion	Yes	Yes	Same
cDWI	Yes	Yes	Same
CEST	Yes	Yes	Same
DB SWI	Yes	Yes	Same
DCE	Yes	Yes	Same
DTI	Yes	Yes	Same
Multiband	Yes	Yes	Same
FACT	Yes	Yes	Same
4D Flow	Yes	Yes	Same
2D Flow	Yes	Yes	Same
FSE DWI	Yes	Yes	Same

ITEM	Proposed Device uMR Ultra	Predicate Device uMR Omega	Remark
FSP+	Yes	Yes	Same
MARS+	Yes	Yes	Same
MATRIX	Yes	Yes	Same
MicroView	Yes	Yes	Same
MQD	Yes	No	Note 16
3D MRCP	Yes	Yes	Same
MRE	Yes	Yes	Same
Respiratory Navigator	Yes	Yes	Same
NCEMRA	Yes	Yes	Same
SNAP	Yes	Yes	Same
SWI	Yes	Yes	Same
SWI+	Yes	Yes	Same
T1rho	Yes	Yes	Same
tFAST	Yes	Yes	Same
TRASS	Yes	Yes	Same
uCS	Yes	Yes	Same
uCSR	Yes	Yes	Same
uFreeR	Yes	Yes	Same
uSWIFT	Yes	Yes	Same
UTE	Yes	Yes	Same
WFI	Yes	Yes	Same
QScan	Yes	Yes	Same
Myocardial Perfusion Imaging	Yes	Yes	Same
Cardiac Function Imaging	Yes	Yes	Same
Myocardial Tagging Imaging	Yes	Yes	Same
Myocardial Mapping Imaging	Yes	Yes	Same
MRCA	Yes	Yes	Same
Silicone-Only Imaging	Yes	Yes	Same

ITEM	Proposed Device uMR Ultra	Predicate Device uMR Omega	Remark
Inline MOCO	Yes	Yes	Same
Inline ECV	Yes	Yes	Same
Workflow			
EasyScan	Yes	Yes	Same
MoCap	Yes	Yes	Same
EasyBolus	Yes	No	Note 17
Auto Bolus Tracker	Yes	No	Note 18
Breast Biopsy	Yes	Yes	Same
Inline CEST	Yes	No	Note 19
TI Scout	Yes	Yes	Same
EasyFACT	Yes	Yes	Same
EasyCrop	Yes	Yes	Same
Image Reconstruction			
ACS	Yes	Yes	Same
DeepRecon	Yes	Yes	Same
t-ACS	Yes	No	Note 20
AiCo	Yes	No	Note 21
SparkCo	Yes	Yes	Same
Inline Maps	Yes	Yes	Same
Spectroscopy			
CSI MRS Head	Yes	Yes	Same
CSI MRS Prostate	Yes	Yes	Same
SVS MRS Head	Yes	Yes	Same
SVS MRS Breast	Yes	Yes	Same
SVS MRS Liver	Yes	Yes	Same
SVS MRS Prostate	Yes	Yes	Same
Other Functions			
EasyRegister	Yes	No	Note 22
Implant Safety Mode	Yes	Yes	Same
uRemote Assistant	Yes	Yes	Same
Note 1	The patient-accessible bore dimension of the proposed device is smaller than that of the predicate device, which satisfies the clinical applications.		

	The difference did not raise new safety and effectiveness concerns.
Note 2	The max gradient amplitude of the proposed device is larger than that of the predicate device. Peripheral nerve stimulation and cardiac stimulation was controlled according to IEC 60601-2-33. The difference did not raise new safety and effectiveness concerns.
Note 3	The amplifier peak power per channel of the proposed device is the same as one configuration of the predicate device. The difference did not raise new safety and effectiveness concerns.
Note 4	The number of receive channels of the proposed device is more than that of the predicate device. The difference did not raise new safety and effectiveness concerns.
Note 5	The intended use of UHD SuperFlex Large - 24 is equivalent to previously cleared SuperFlex SuperFlex Large - 12. 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 6	The intended use of UHD SuperFlex Small - 24 is equivalent to previously cleared SuperFlex SuperFlex Small - 12. 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 7	The intended use of SuperFlex Whole Body - 48 is equivalent to previously cleared SuperFlex Body - 24. 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 8	The intended use of UHD SuperFlex Free - 24 is identical to previously cleared Head & Neck Coil - 48 (except imaging of head). The difference between them is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.
Note 9	The intended use of Wrist Coil - 24 is equivalent to previously cleared Wrist Coil - 12. 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 10	The intended use of Shoulder Coil - 24 is equivalent to previously cleared Shoulder Coil - 12. 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 11	Compared to the predicate device, the proposed device added Tilt Support, which is used to support Head & Neck Coil scanning. The new component did not raise new safety and effectiveness concerns.
Note 12	Compared to the predicate device, the proposed device added Positioning Couch-top. Positioning Couch-top has load-bearing and deformation requirements. It is determined according to clinical needs and product characteristics. The new component did not raise new safety and effectiveness concerns.
Note 13	Compared to the predicate device, the proposed device added Coil Support. Coil Support can achieve the purpose of being as close as possible but not in contact with the human body through the adjustment mechanism. The internal space and adjustment range can adapt to different body types of people. The new component did not raise new safety and effectiveness concerns.
Note 14	Compared to the predicate device, the proposed device added Patient Bore Projector, which projects the video into the bore for patients to watch during scanning to improve patient comfort. The new function did not raise new safety and effectiveness concerns.

Note 15	Compared to the predicate device, the proposed device added Body Part Recognition function in uVision, which allows assist patient positioning by performing image recognition on human natural images through a 3D camera during the positioning stage. The new function did not raise new safety and effectiveness concerns.
Note 16	MQD is substantially equivalent to GRE without RF Spoiling and use varying flip angle and/or repetition time to acquire T1 mapping and T2 mapping images. The new function did not raise new safety and effectiveness concerns.
Note 17	EasyBolus is a workflow feature that combines the EasyScan function and the AutoBolusTracer function, capable of automatically locating the Bolus protocol and its ROI (Region of Interest), and observing changes in signal values within the ROI to automatically trigger the next protocol. The positioning can also be adjusted manually by user. If the user is not satisfied with the timing of the trigger, manual triggering is also possible. The user panel also supports user configuration for manual triggering. The new function did not raise new safety and effectiveness concerns.
Note 18	Auto Bolus Tracker is a feature that automatically recognizes the time when the contrast agent reaches the target position and triggers the scan. The new function did not raise new safety and effectiveness concerns.
Note 19	Inline CEST aims to calculate the images of Z-spectrum curve and MTRAsym curve from the data in ROI from S0, Ssat and B0Map. The new function did not raise new safety and effectiveness concerns.
Note 20	t-ACS (temporal AI-assisted Compressed Sensing) is a dynamic magnetic resonance imaging technique which combines traditional Compressed Sensing algorithm with deep learning priors. It outputs multi-phase images. The new function did not raise new safety and effectiveness concerns.
Note 21	AiCo (AI-based Motion Correction) is a k-space based technique to suppress motion artifacts. After enabling the AiCo function, the original images will still be saved. The new function did not raise new safety and effectiveness concerns.
Note 22	EasyRegister is a function that automatic estimates patient's height and weight and patient position by performing regression on human natural images through a 3D camera during the positioning stage. Based on the captured feature and estimated pose of the patient on the table. The new function did not raise new safety and effectiveness concerns.

Table 2 Comparison to reference device#1

ITEM	Proposed Device uMR Ultra	Reference Device#1 uWS-MR (K220332)	Remark
Image Processing			
Inline Cardiac Function	Yes	Yes	Note 23
Inline MRS	Yes	Yes	Same
Inline CPR	Yes	Yes	Same
Inline BOLD	Yes	Yes	Same
Inline DTI	Yes	Yes	Same
Inline Perfusion	Yes	Yes	Same

ITEM	Proposed Device uMR Ultra	Reference Device#1 uWS-MR (K220332)	Remark
Workflow			
Inline Stitching	Yes	Yes	Same
Note 23	In this submission, inline ED/ES phase recognition was included in the inline cardiac function module. Cardiac MR cine imaging captures multi-slice data with varying end-systolic (ES) and end-diastolic (ED) phases in the absence of triggering signals (e.g., ECG). The inline ED/ES recognition algorithm automatically identifies these phases per slice, enabling cross-slice cardiac cycle alignment for functional analysis. The difference did not raise new safety and effectiveness concerns.		

Table 3 Comparison to reference device#2

ITEM	Proposed Device uMR Ultra	Reference Device#2 uPMR 790 (K234154)	Remark
Workflow			
PASS	Yes	Yes	Same
ImageGuard	Yes	Yes	Same

8. Performance Date

The following testing was conducted on uMR Ultra and were provided in support of the substantial determination.

Non-Clinical Testing

Non-clinical testing including image performance tests were conducted for uMR Ultra 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.

- Various testing has been conducted (such as performance testing for ACS, DeepRecon, EasyScan, t-ACS, AiCo, SparkCo, ImageGuard, EasyCrop, Auto Bolus Tracker, Cardiac T2 Mapping, T2 Star Mapping, CEST, Easy FACT, FACT, 3D ASL, Auto TI Scout, MQD, MRE, Silicone-Only Imaging, Inline MOCO, Inline Cardiac Function, ECV, uVision, EasyRegister, Breast Biopsy, Inline CEST, uRemote Assistant, T1rho, Mocap, SVS-MEGA, MRS Breast, MRS PRESS, MRS Prostate, Liver MRS, MRS HISE, MRS STEAM, Cardiac T1 mapping, QScan, MARS+, 4D Flow and 2D Flow).
- Sample clinical images for all clinical sequences and coils were reviewed by three U.S. board-certified radiologists 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

● 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 K220332. In addition, we have conducted additional validation on the uMR Ultra system with 749 samples from 25 volunteers, with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups.

Subjects' Characteristics	Total(N=25)
Gender	Number
Male	15
Female	10
Age	
18-28	5
29-40	7
>41	13
Ethnicity	
White	4
Asian	16
Black	5
Body Mass Index (BMI)	
Underweight (<18.5)	2
Healthy weight (18.5-24.9)	18
Overweight and obesity (>24.9)	5

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 the table below.

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 within a line-pair test object 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.

● DeepRecon

DeepRecon is a deep-learning based image processing algorithm for intelligent image de-noising and K-space-interpolation based image super-resolution.

The training data of DeepRecon were collected from 264 volunteers. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulted in a total of 165,837 samples. In terms of the ground truth and input images in training dataset, the multiple-averaged images with high-resolution and high SNR were collected as the ground-truth images. The input images were generated from the ground-truth images by sequentially reducing the SNR and resolution of the ground-truth images. All data were manually quality controlled before included for training.

The DeepRecon had already received FDA cleared for the uMR Omega system, with the approval number K243122. In uMR Omega system, the DeepRecon had undergone performance testing on 77 US subjects with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups. In addition, validation on the uMR Ultra system was conducted with 25 volunteers (nearly 2200 samples) with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups.

Subjects' Characteristics	Total(N=25)
Gender	Number
Male	16
Female	9
Age	
18-28	10
29-50	12
>50	3
Ethnicity	
White	10
Asian	10
Black	5
Body Mass Index (BMI)	
< 18.5	10

18.5-24.9	12
> 24.9	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 had no overlap with the training data and were completely independent. No clinical subgroups and confounders had been defined for the datasets. Both NADR (without DeepRecon) and DeepRecon results were generated for each sample, and NADR and DeepRecon results were evaluated based on metrics referenced in magnetic resonance literature, such as image SNR, image uniformity, image contrast and structure measurement. The acceptance criteria for performance testing and the corresponding testing results can be found in the table below.

Evaluation Item	Acceptance Criteria	Test Result	Results
Image SNR	DeepRecon images achieve higher SNR compared to NADR images	NADR: 343.63	PASS
		DeepRecon: 496.15	
Image uniformity	Uniformity difference between DeepRecon images and NADR images under 5%	0.07%	PASS
Image contrast	Intensity difference between DeepRecon images and NADR images under 5%	0.2%	PASS
Structure measurement	Measurements on NADR and DeepRecon images of same structures, measurement difference under 5%	0%	PASS

The DeepRecon had been validated to provide image de-noising and super-resolution processing using various ethnicities, age groups, BMIs, and pathological variations. In addition, DeepRecon images were evaluated by American Board of Radiologists certificated physicians, covering a range of protocols and body parts. Clinical protocols varied contrast such as T1, T2, T1Flair, T2Flair, PD, STIR, etc. The evaluation reports from radiologists verified that DeepRecon meets the requirements of clinical diagnosis. All DeepRecon images were rated with equivalent or higher scores in terms of diagnosis quality.

● EasyScan

EasyScan is a workflow feature that automatically locates slice groups. This function is based on deep learning algorithms, which identify, locate or segment specific tissue structures in images, and calculate the position and orientation of slice groups to achieve automatic placement of slice groups. The output results need to be manually

confirmed by the user, and manual movement of the lamellar group position is supported.

Acceptance Criteria

To verify the EasyScan of the algorithm, the subjective evaluation method was used.

Pass with auto positioning (P1): The auto slice positioning meets the user's requirement.

Pass with user adjustment (P2): The slice positioning requires further adjustment by the user.

Fail (F): Auto position not generated or cannot be adjusted afterwards.

Test pass criteria: No Fail cases and auto position success rate $P1/(P1+P2+F)$ exceeds 80%

Testing Data Information

The EasyScan has undergone performance testing on 444 cases from 116 subjects with diverse demographic distributions covering various genders, age groups and ethnicities.

The EasyScan has undergone performance testing on various body parts 13 body parts (include head, abdomen, cpine, tspine, lspine, shoulder, cardiac, knee, pelvis, hip, ankle, breast, thorax)

Subjects' Characteristics	Total(N=116)
Gender	Number
Male	68
Female	48
Age	
<29	43
29-40	25
> 41	48
Magnetic field strength (T)	
1.5	24
3	92
Ethnicity	
Black	31
White	56
Asian	29

Equipments and Protocols:

The data were acquired from 1.5T and 3T magnetic resonance imaging equipment from UIH. The data were easyscout data.

Clinical Subgroups:

EasyScan is a workflow function that allows automatic slice positioning for imaging. The positioning can also be adjusted manually by user. The final positioning effect is equivalent to manual operation without EasyScan feature. And no clinical subgroups

and confounders have been defined for the datasets

Testing & Training Data Independence

The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data is entirely independent and does not share any overlap with the training data.

The pass criteria of EasyScan feature is 99.6%, and the results evaluated by the licensed MRI technologist with U.S. credentials. Therefore, EasyScan meets the criteria for safety and effectiveness, and EasyScan can meet the requirements for automatic positioning locates slice groups.

● **t-ACS**

t-ACS (temporal AI-assisted Compressed Sensing) is a dynamic magnetic resonance (MR) imaging technique, which utilizes the low-rank characteristics of time dimension, physical model and deep learning priors. t-ACS technique reconstructs multi-phase MR data and outputs multi-phase images.

Performance test

In order to validate the performance of t-ACS algorithm, i) quantification test, ii) local structure measurement and iii) temporal image performance test were conducted on test data for all three t-ACS application types.

i) Quantification test was conducted based on MAE, PSNR and SSIM, which were global metrics for evaluating difference or similarity between two images.

ii) Local structure measurement was conducted: sizes of the same structure of t-ACS images and fully sampled images were measured by distance measurement tool of the UIH image processing software on uMR Ultra system.

iii) The motion-time curve was used in temporal image performance test and was obtained by delineating ROIs in each phase of the image, calculated the average signal intensity within the regions, and then plotted the values on a coordinate graph with frame number on the horizontal axis and temporal variation on the vertical axis. Additionally, the average signal values within ROIs were subjected to consistency measurement through Bland-Altman analysis.

Test Result

Firstly, the performance test of t-ACS includes two parts:

(1) AI Module Test (focused on the AI module alone).

(2) t-ACS Integration Test (encompassing the t-ACS framework as a whole, as described in submitted t-ACS performance evaluation report).

Then, all the test results are summarized as follows:

(1) AI Module Test

AI prediction (AI module output) was much closer to the reference comparing to the AI module input images in all three t-ACS application types.

(2) t-ACS Integration Test

- 1) A better consistency between t-ACS and the reference than that between CS and the reference was shown in all t-ACS application types.
- 2) No large structural difference appeared between t-ACS and the reference in all t-ACS application types.
- 3) The motion-time curves and Bland-Altman analysis showed the consistency between t-ACS and the reference based on simulated and real acquired data in all t-ACS application types.

Data Information

The training and validation datasets were collected from 108 volunteers, each volunteer was scanned by uMR Ultra scanners for multiple body parts and clinical protocols, resulting in a large number of samples. Fully-sampled k-space data were collected and transformed into image domain as reference. The input data were generated by sub-sampling the fully-sampled k-space data. All data were manually quality controlled before included for training.

t-ACS has undergone performance testing on 1173 cases from 60 volunteers covering various genders, age groups, ethnicities and BMI groups as shown in the tables below.

Subjects' Characteristics	Total(N=60)
Gender	Number
Male	41
Female	19
Age	
18-28	25
29-40	15
> =41	20
Ethnicity	
White	24
Black	9
Asian	27
BMI	
<= 24.9	37
> 24.9	23

Body part /Phantom	Dynamic MRI scan applications	Number of cases
HEAD	Type I: Non-periodic physiological movement	136
SPINE	Type I: Non-periodic physiological movement	132
HIP	Type I: Non-periodic physiological movement	106
CARDIAC	Type II: Cardiac periodic movement	25

KNEE	Type I: Non-periodic physiological movement	131
ABDOMEN	Type III: Contrast enhancement	186
	Type I: Non-periodic physiological movement	94
PELVIS	Type III: Contrast enhancement	52
	Type I: Non-periodic physiological movement	149
ANKLE	Type I: Non-periodic physiological movement	94
PHANTOM	Type I: Non-periodic physiological movement	68

Equipments and Protocols

The test data were acquired by uMR Ultra scanners, which covered representative protocols in clinical practice such as T1, T2 and PD with and without fat saturation.

Clinical Subgroups and Confounders

No clinical subgroups and confounders have been defined for these datasets.

Independence of Training and Testing Data

The testing data were collected independently from the training data, with different time periods. Therefore, the testing data were entirely independent and didn't share any overlap with the training data.

The t-ACS on uMR Ultra was shown to perform better than traditional Compressed Sensing in the sense of discrepancy from fully sampled images and PSNR using images from various age groups, BMIs, ethnicities and pathological variations. The structure measurements on paired images verified that same structures of t-ACS and reference were significantly the same. And t-ACS integration tests in all applications proved that t-ACS had good agreement with the reference.

● AiCo

In clinical magnetic resonance imaging (MRI) scans, patient movement can produce artifacts in the image that can affect diagnosis. AiCo (AI-based Motion Correction) is a k-space based technique to suppress motion artifacts. When AiCo parameter is enabled, motion-corrected images will be generated, while the original images will also be retained.

AiCo is not a diagnostic function, no clinical subgroups have been defined for the datasets.

The training dataset for the AI module in AiCo was collected from various anatomies, image contrasts, and acceleration factors. It includes data from 114 volunteers. Each

participant was scanned using UIH MRI systems across multiple body parts and clinical protocols, resulting in a total of 140,000 images. All data were quality-controlled before being included in the training process.

AiCo has undergone performance evaluation on 24 healthy volunteers. The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. In the context of AiCo performance evaluation, the gold standard reference data refers to motionless data collected from the same individual during the same time period. The instruction during gold standard data collection is to remain still, while motion data is obtained using various movement instructions specific to different body parts and protocols. Each volunteer was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulting in 218 samples, which cover representative protocols in clinical practice such as T1, T2, PD with and without fat saturation. The demographic distribution was listed in table below.

Subjects' Characteristics	Total(N=24)
Gender	Number
Male	12
Female	12
Age	
18-28	8
29-40	11
>41	5
Body Mass Index (BMI)	
Under and healthy weight (<24.9)	10
Overweight and obesity (>24.9)	14
Ethnicity	
White	7
Black	5
Asian	12
Body parts	Number of Cases
Head	20
Neck	23
Shoulder	23
Spine	28
Thorax	12
Abdomen	14
Cardiac	9
Pelvis	27
Hip	15
Knee	16
Ankle	18
Upper Extremity	13

The performance evaluation of AiCo consists of two parts: The Quantification Test and the Local Structural Measurements Test. The Quantification Test quantitatively

compares the PSNR and SSIM values of images processed by AiCo against the original images. Meanwhile, the Local Structural Measurements Test assesses the structural dimensions of images before and after AiCo processing, focusing on the ability of AiCo to retain image details. Results indicate that AiCo images exhibit improved PSNR and SSIM compared to the originals in the Quantification Test, with no significant structural differences from the gold standard in the Local Structural Measurements, across all gender, age, BMI, and ethnicity groups. Additionally, images collected from volunteers representing diverse anatomies and demographics using the AiCo technique were reviewed by three U.S. certified radiologists. They confirmed that the image quality of AiCo images is diagnostically acceptable, and compared to images without AiCo, AiCo images exhibit fewer motion artifacts and offer greater benefits for clinical diagnosis.

● **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 the detected spark artifacts and reduce the appearance of spark artifacts.

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 5.

Subjects' Characteristics	Total(N=15)
Gender	Number
Male	9
Female	6
Age	
18-29	2
30-44	8
45-64	4
>=65	0
Ethnicity	
White	N.A.
Asian	15
Body Mass Index (BMI)	
Underweight (<18.5)	2
Healthy weight (18.5-24.9)	10
Overweight (25.0-29.9)	3
Obesity (>=30.0)	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.

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 6 shows.

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 Based on the real-world spark dataset, evaluating the image quality improvement between the spark-corrected images and spark images by one experienced evaluator.	The average PSNR of spark-corrected images need to be higher than the spark images. Spark artifacts need to be reduced or corrected after enable the SparkCo.	The average PSNR of spark-corrected images is 1.6 higher than the spark images. The images with spark artifacts were successfully corrected after enable the SparkCo.
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In summary, SparkCo meets the criteria for safety and effectiveness, and can used to detect and correct spark artifacts for improving image quality.

● ImageGuard

In clinical magnetic resonance imaging (MRI) scans, patient movement can produce artifacts in the image; ImageGuard is a workflow function, which is expected for automatic monitoring of MR images for motion artifacts and providing real-time prompts to assist technicians in image quality control. And the prompts do not affect scanning process.

Acceptance Criteria

To verify the ImageGuard of the algorithm, the subjective evaluation method was used. The test pass criteria was: Success rate $P/(P+F)$ exceeds 90%.

Pass(P): There are two scenarios which meet the pass requirements, including

- (1) The volunteers move, the image quality does not meet the users' requirements, and the prompt appears;
- (2) The volunteers do not move, the image quality meets the users' requirements, and the prompt does not appear.

Fail (F): There are two scenarios which the tests will fail, including

- (1) The volunteers move, the image quality does not meet the users' requirements, and the prompt does not appear;
- (2) The volunteers do not move, the image quality meets the users' requirements, and the prompt appears.

Test pass criteria: Success rate $P/(P+F)$ exceeds 90%.

Testing Data Information

The ImageGuard has undergone performance testing with 191 cases from 80 subjects with diverse demographic distributions covering various genders, age groups and ethnicities.

Subjects' Characteristics	Total(N=80)
Gender	Number
Male	45
Female	35
Age	
≤25	14
26-50	47
≥51	19
Magnetic field strength (T)	
1.5	31
3	49
Ethnicity	
White	35
Black	21
Asian	24

Equipments and Protocols:

The data were acquired from 1.5T and 3T magnetic resonance imaging equipment from UIH. The data were FSE and GRE sequence data, including T2, T1, PD contrast.

Clinical Subgroups:

ImageGuard is a workflow function, which is expected for automatic monitoring of MR images for motion artifacts and providing real-time prompts to assist technicians in image quality control. And the prompts do not affect scanning process. And no clinical subgroups and confounders have been defined for the datasets.

Testing & Training Data Independence

The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data is entirely independent and does not share any overlap with the training data.

The pass criteria of ImageGuard feature is 100%, and the results evaluated by the licensed MRI technologist with U.S. credentials. Therefore, ImageGuard meets the criteria for safety and effectiveness.

● **EasyCrop**

EasyCrop is a function that enables automatic cropping of images scanned with the MRA images to simplify the workflow, which allows users to obtain interference-free MIP images and automatically rotated MIP images with different angles when the scan is completed and images are generated. After enabling the EasyCrop function, the original images of MRA images will still be saved.

Acceptance Criteria

To verify the EasyCrop of the algorithm, the subjective evaluation method was used. The test pass criteria was: No Fail cases and pass rate $P1 / (P1 + P2 + F)$ exceeds 90%.

Pass(P1): The other peripheral tissues are cropped, and the cropped images meet the users' requirements.

Pass(P2): The cropped images do not meet the users' requirements and the users can re-crop the original images in review3D.

Fail (F): EasyCrop does not operate successfully, or the original images are not saved

Test pass criteria: No Fail cases and pass rate $P1 / (P1 + P2 + F)$ exceeds 90%.

Testing Data Information

The EasyCrop has undergone performance testing on 5 intended imaging body parts (head vessels, carotid vessels, renal vessels, pancreaticobiliary and lower extremity vessels) with diverse demographic distributions covering various genders, age groups.

Subjects' Characteristics	Total(N=65)
Gender	Number
Male	37
Female	28
Age	
<29	23
29-40	9
> 40	33
Magnetic field strength (T)	
1.5T	18
3.0T	47
Ethnicity	
Asian	12
Black	19
White	34

Equipments and Protocols:

The data were acquired from 1.5T and 3T magnetic resonance imaging equipment from UIH. The data were FSE and GRE sequence data.

Clinical Subgroups

EasyCrop is a function that enables automatic cropping of images scanned with the MRA images to simplify the workflow, after enabling the EasyCrop function, the original images of MRA images will still be saved. Therefore, no clinical subgroups and confounders have been defined for the datasets.

Testing & Training Data Independence

The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data is entirely independent and does not share any overlap with the training data.

The pass criteria of EasyCrop feature is 100%, and the results evaluated by the licensed MRI technologist with U.S. credentials. Therefore, EasyCrop meets the criteria for safety and effectiveness, and EasyCrop can meet the requirements for automatic cropping.

● EasyFACT

EasyFACT workflow, based on the FACT sequence, automatically places the ROI (Regions of Interest) of 5 suitable locations on the liver.

Acceptance Criteria

The validation type and acceptance criteria is shown in the table below.

Validation Type	Acceptance Criteria
Passing Rate	Satisfied and Acceptable ratio $(S+A)/(S+A+F)$ exceeds 95%. Satisfied (S): Five ROIs are placed within the liver parenchyma, avoiding the liver borders and vascular structures. Acceptable (A): Fewer than five ROIs are placed within the liver parenchyma, avoiding the liver borders and vascular structures. Failure (F): ROIs are positioned on liver borders or vascular structures, or no ROIs are placed.

Testing Data Information

The distribution of volunteer dataset used for validation is listed in the table below. A total of 25 cases from 25 volunteers were used.

Subjects' Characteristics	Total(N=25)
Gender	Number
Male	20
Female	5
Age	
<30	6
[30,40)	7
[40,50)	6
[50,60)	3
[60,70)	2
>=70	1
Weight (kg)	
<80	14

[80, 90)	4
>=90	7
Ethnicity	
Asian	11
White	9
Black	5

Performance Testing Summary

Subjective evaluation results of 25 volunteers: satisfied and acceptable ratio is 100%. Meanwhile, the subgroup analysis shows that the EasyFACT workflow has good generalization in different subgroups.

Gender	Satisfied (S)	Acceptable (A)	Failure (F)	Satisfied and Acceptable Ratio
Male	100%	0%	0%	100%
Female	100%	0%	0%	100%
Age				
<30	100%	0%	0%	100%
[30,40)	100%	0%	0%	100%
[40,50)	100%	0%	0%	100%
[50,60)	100%	0%	0%	100%
[60,70)	100%	0%	0%	100%
>=70	100%	0%	0%	100%
Weight (kg)				
<80	100%	0%	0%	100%
[80, 90)	100%	0%	0%	100%
>=90	100%	0%	0%	100%
Ethnicity				
Asian	100%	0%	0%	100%
White	100%	0%	0%	100%
Black	100%	0%	0%	100%

Testing& Training Data Independence

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

● Auto TI Scout

Auto TI Scout is a function that automatically detects the TI frame which has the darkest ventricular myocardium of the TIScout image, allowing users to achieve the best inversion time (TI).

Acceptance Criteria

Test procedure, acceptance method, and acceptance criteria is shown in the table below.

Validation Type	Acceptance Criteria
Error between TI frame output by algorithm and gold standard	The average frame difference between the frame of auto-calculated TI and the gold standard frame is less than or equal to 1 frame, and the maximum frame difference is less than or equal to 2 frames.

Testing Data Information

A total of 27 patients were used as the test data. The distribution is as the following table.

Subjects' Characteristics	Total(N=27)
Gender	Number
Male	18
Female	9
Age	
<18	1
18-28	4
29-40	7
> 41	15
Protocol	
TIscout_sax	27
BMI (kg/m(2))	
<18.5	1
[18.5, 25)	10
>=25	11
Unknown	5
Magnetic field strength (T)	
1.5	18
3	9
Ethnicity	
Asian	19
White	8

Performance Testing Summary

According to the subgroup analysis in the table below, it can be seen that the TI Scout algorithm performs as expected in different subgroups.

Gender	Number	Average frame difference	maximum frame difference
Male	18	0.38	2
Female	9	0.44	1
Age			

<18	1	0	0
18-28	4	0.25	1
29-40	7	0.57	2
> 41	15	0.33	1
Protocol			
TIscout_sax	27	0.37	2
BMI (kg/m(2))			
<18.5	1	0	0
[18.5, 25)	10	0.7	2
>=25	11	0.27	1
Unknown	5	0	0
Magnetic field strength (T)			
1.5	18	0.39	2
3	9	0.33	1
Ethnicity			
Asian	19	0.47	2
White	8	0.125	1

Testing & Training Data Independence

The training data used for the training of the TI Scout algorithm is independent of the data used to test the algorithm.

● Inline MOCO

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.

Acceptance Criteria

The validation type and acceptance criteria is shown in the table below.

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:

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.

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:

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.

Subgroup	Details of each subgroup	Number of cases
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 the proposed device algorithm has good generalization in different subgroups.

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	0.93
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 the proposed device algorithm has good generalization in different subgroups.

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.

● **Inline Cardiac Function**

Inline cardiac function includes inline cardiac function calculation and inline ED/ES Phases Recognition.

The algorithms of inline Cardiac function calculation are the same in uWS-MR (K220332) Cardiac Analysis.

Inline ED/ES phases recognition algorithm (AI) is used to get the ED and ES Phases for the cardiac images automatically for the inline cardiac function.

Inline ED/ES Phases Recognition

Inline ED/ES phases recognition algorithm(AI) is used to get the ED and ES Phases for the cardiac images automatically for the inline cardiac function.

Acceptance Criteria

The validation type and acceptance criteria is shown in the table below.

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.

Testing Data Information

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

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	26	26
Black	8	9

Performance Testing Summary

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.

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	26	0.33
Black	9	0.13

Testing& Training Data Independence

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

Inline ECV segmentation (AI) is used to obtain the ROI within the left ventricular blood pool for the inline ECV.

Acceptance Criteria

The validation type and acceptance criteria is shown in the table below.

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 are 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.

Testing Data Information

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.

Subjects' Characteristics	Total(N=28)
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
Positive	4
Unknown	5

Performance Testing Summary

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

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%
Positive	100%	0%	0%	100%
Unknown	100%	0%	0%	100%

Testing & Training Data Independence

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

● **EasyRegister**

EasyRegister estimates patient's height and weight by performing regression on human natural images through a 3D camera during the positioning stage. Based on the captured feature and estimated pose of the patient on the table, **EasyRegister** enables height estimation of the patient and weight estimation of the patient.

1) Height Estimation

A total of 118 cases from 63 patients were used as the test data. For each patient, it had the precisely measured height value. The distribution is as the following Figures.

Evaluation indicators

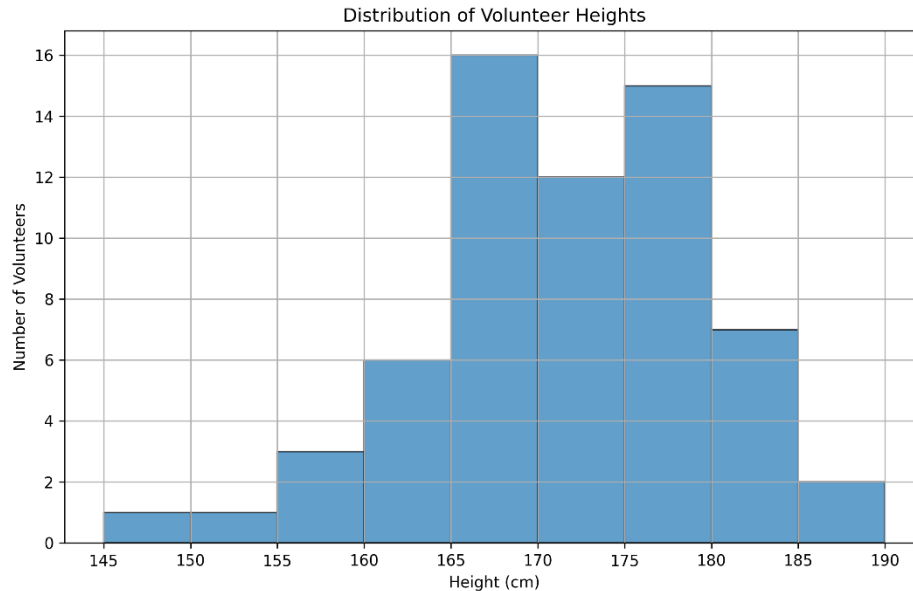
The ground truth for the height data of volunteers is measured by using physical examination standards to determine the height values of each volunteer.

The validation type and acceptance criteria is

1. PH5(Percentage of height error within 5%);
2. PH15(Percentage of height error within 15%);
3. MEAN_H (Average error of height).

Testing Data Information

A total of 118 cases from 63 patients were used as the test data. This dataset covers multiple ethnic groups, including Chinese (57), US (4), France (1), and Germany (1). For each patient, it had the precisely measured height value. The height distribution is as the following figure.



Performance Testing Summary

The performance of the height estimation algorithm is shown in the table below.

Algorithm	PH5	PH15	MEAN_H
Human height estimation	92.4%	100%	31.53mm

Testing & Training Data Independence

The training data used for the training of the height estimation algorithm is independent of the data used to test the algorithm.

2) Weight Estimation

A total of 118 cases from 63 patients were used as the test data. For each patient, it had the precisely measured weight value. The distribution is as the following figure.

Evaluation indicators

The ground truth for the weight data of volunteers is measured by using physical examination standards to determine the weight values of each volunteer.

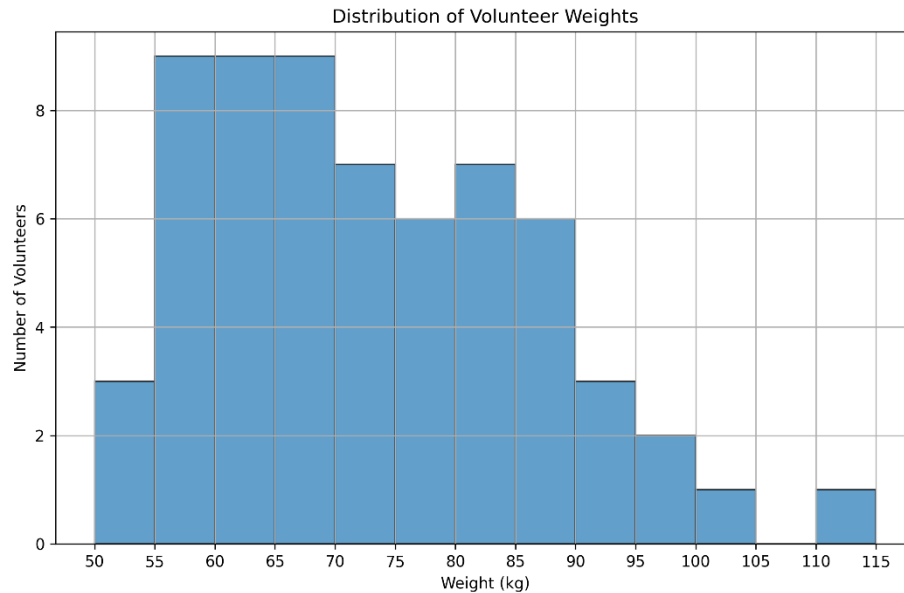
The validation type and acceptance criteria is

1. PW10(Percentage of weight error within 10%);
2. PW20(Percentage of weight error within 20%)
3. MEAN_W (Average error of weight)

Testing Data Information

A total of 118 cases from 63 patients were used as the test data. This dataset covers multiple ethnic groups, including Chinese (57), US (4), France (1), and Germany (1).

For each patient, it had the precisely measured weight value. The weight distribution is as the following figure.



Performance Testing Summary

The performance of the height estimation algorithm is shown in the table below.

Algorithm	PW10	PW20	MEAN_H
Human weight estimation	68.64%	90.68%	6.18kg

Testing & Training Data Independence

The training data used for the training of the weight estimation algorithm is independent of the data used to test the algorithm.

● EasyBolus

EasyBolus is a workflow function that achieved full-process automation of enhanced scanning through EasyScan and Auto Bolus Tracker. EasyBolus is a combination of the aforementioned features, with only new interface parts added, and the algorithm parts are completely reused. The EasyScan algorithm is an artificial intelligence algorithm that utilizes neural networks, while the Auto Bolus Tracker is a traditional algorithm that does not use AI.

Acceptance Criteria

The details of the automatic positioning can be found in the EasyScan test report, and the results of the automatic triggering can be found in the Auto Bolus Tracker report.

To test the combination of EasyScan and Auto Bolus Tracking features performs as expected, the subjective evaluation method was used.

The evaluation results for EasyBolus are carried out by certified professionals in the United States.

The test pass criteria was: No Fail cases and success rate $P1+P2/(P1+P2+F)$ exceeds 100%.

Pass with level 1 (P1): The monitoring point positioning meets the user's requirements and the frame difference between the frame of auto bolus tracker and the result judged by experienced MRI technologists frame is less than or equal to 1 frame.

Pass with level 2 (P2): The monitoring point positioning meets the user's requirements and the frame difference between the frame of auto bolus tracker and the result judged by experienced MRI technologists is 2 frames.

Fail (F): Auto position not generated or cannot be adjusted afterwards or the frame difference between the frame of auto bolus tracker and the result judged by experienced MRI technologists is larger than 2 frames.

Testing Data Information

The EasyBolus has undergone performance testing on 20 subjects

Subjects' Characteristics	Total(N=20)
Gender	Number
Male	12
Female	8
Age	
<60	11
>60	9
Protocol	
neck_easy_scout	20
BolusTracker_cor	20
Magnetic field strength (T)	
3.0	20
Ethnicity	
Asia	20

The algorithm used in EasyScan is AI-based, and the test data for EasyScan incorporates information on various genders, ages, and ethnicities. For further details, please refer to the EasyScan summary. We have conducted tests across different genders, ages, and ethnicities. In contrast, Auto Bolus Tracker is not AI-driven; it is solely concerned with variations in image brightness, making it unrelated to the gender, age, or ethnicity of the test data. Therefore, no special considerations were made regarding these factors during the testing process.

Performance Testing Summary

Pass with level 1 (P1) = 80%

Pass with level 2 (P2) = 20%

Total Failure Rate = 0%

Pass = 100%

Testing & Training Data Independence

The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data is entirely independent and does not share any overlap with the training data.

Summary

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

9. Conclusions

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.