



May 22, 2026

Shanghai United Imaging Healthcare Co., Ltd.
Gao Xin
RA Manager
#2258 Chengbei Rd. Jiading District
Shanghai, 201807
China

Re: K260113
Trade/Device Name: uMR Astra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: April 26, 2026
Received: April 27, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is positioned over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, PhD
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

K260113

?

Please provide the device trade name(s).

?

uMR Astra

Please provide your Indications for Use below.

?

The uMR Astra system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510 (k) SUMMARY

1. Date of Preparation

August 22, 2025

2. Sponsor Identification

Shanghai United Imaging Healthcare Co.,Ltd.

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

Contact Person: Xin GAO

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3. Identification of Proposed Device

Trade Name: uMR Astra

Common Name: Magnetic Resonance Imaging System

Model: uMR Astra

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: K243547

Device Name: uMR Ultra

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: LNH

Review Panel: Radiology

Reference device#1

510(k) Number: K243122

Device Name: uMR Omega

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: LNH, MOS

Review Panel: Radiology

Reference device#2

510(k) Number: K220332

Device Name: uWS-MR

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ, QIH

Review Panel: Radiology

5. Device Description

uMR Astra 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 Astra 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 Astra 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 Astra	Predicate Device uMR Ultra (K243547)	Remark
Indications for Use	The uMR Astra 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 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.	Same

Table 2 Comparison to Predicate device

ITEM	Proposed Device uMR Astra	Predicate Device uMR Ultra (K243547)	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	70 cm	Same
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	≤ 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 Astra	Predicate Device uMR Ultra (K243547)	Remark
	≤ 0.002 ppm @ 10cm DSV		
Gradient system			
Max gradient amplitude	50 mT/m	100 mT/m	Note 1
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	20 kW	20 kW	Same
Maximum number of receive channels	144	192	Note 2
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	Yes	Same
SuperFlex Small - 12	Yes	Yes	Same
UHD SuperFlex Small - 24	Yes	Yes	Same
SuperFlex Body - 24	Yes	Yes	Same
SuperFlex Whole Body - 48	Yes	Yes	Same
Head Coil - 16	Yes	Yes	Same
Head & Neck Coil - 24	Yes	Yes	Same
Head & Neck Coil - 48	Yes	Yes	Same
UHD SuperFlex Neck & Chest - 24	Yes	Yes	Note 3
Infant Coil - 24	Yes	Yes	Same
Small Loop Coil	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
Wrist Coil - 24	Yes	Yes	Same

ITEM	Proposed Device uMR Astra	Predicate Device uMR Ultra (K243547)	Remark
Tx/Rx Head Coil	Yes	Yes	Same
Shoulder Coil - 12	Yes	Yes	Same
Shoulder Coil - 24	Yes	Yes	Same
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
UHD Head & Neck Coil - 72	Yes	No	Note 4
UHD Neuro-Cardiovascular Coil - 96	Yes	No	Note 5
Patient table			
Maximum supported patient weight	310 kg	310 kg	Same
Accessories			
Vital Signal Monitor	ECG, Respiration and pulse module uVWMERP Wireless gating trigger unit uMVRX	ECG, Respiration and pulse module uVWMERP Wireless gating trigger unit uMVRX	Same
	Respiration module mmw101 (optional)	Respiration module mmw101 (optional)	Same
Tilt Support	Yes	Yes	Same
Positioning Couch-top	Yes	Yes	Same
Coil Support	Yes	Yes	Same
Patient Bore Projector	Yes	Yes	Same
uVision			
Body Part Recognition	Yes	Yes	Same
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

ITEM	Proposed Device uMR Astra	Predicate Device uMR Ultra (K243547)	Remark
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 series	Comply with ISO 10993 series	Same
Surface Heating	NEMA MS 14	NEMA MS 14	Same
Imaging Features			
4D CEMRA 4D Contrast Enhancement Magnetic Resonance Angiography	Yes	Yes	Same
4D NCEMRA 4D Non-Contrast- Enhanced Magnetic Resonance Angiography	Yes	Yes	Same
ARMS Acquisition and Reconstruction with Motion Suppression	Yes	Yes	Same
ARMS DWI ARMS Diffusion- Weighted Imaging	Yes	Yes	Same
3D ASL 3D Arterial Spin Labeling	Yes	Yes	Same
Multi-PLD ASL Multiple Post-Labeling- Delay Arterial Spin Labeling	Yes	Yes	Same
bFAST	Yes	Yes	Same
BOLD Blood Oxygenation Level Dependent imaging	Yes	Yes	Same
Brain Perfusion	Yes	Yes	Same
cDWI computed Diffusion- Weighted Imaging	Yes	Yes	Same
CEST Chemical Exchange Saturation Transfer	Yes	Yes	Same
DB SWI Dark Blood of Susceptibility Weighted Imaging	Yes	Yes	Same

ITEM	Proposed Device uMR Astra	Predicate Device uMR Ultra (K243547)	Remark
DCE Dynamic Contrast Enhancement	Yes	Yes	Same
DTI Diffusion Tensor Imaging	Yes	Yes	Same
Multiband	Yes	Yes	Same
FACT Fat Analysis and Calculation Technique	Yes	Yes	Same
4D Flow 4D Flow Quantification	Yes	Yes	Same
2D Flow 2D Flow Quantification	Yes	Yes	Same
FSE DWI FSE Diffusion-Weighted Imaging	Yes	Yes	Same
FSP+ Fast Spoiled Gradient Echo Plus	Yes	Yes	Same
MARS+ Metal Artifact Reduction Suppression Plus	Yes	Yes	Same
MATRIX Modulated flip Angle Technique in Refocused Imaging with eXtended echo train	Yes	Yes	Same
MicroView	Yes	Yes	Same
MQD MultiQuant Decipher	Yes	Yes	Same
3D MRCP 3D Magnetic Resonance CholangioPancreatography	Yes	Yes	Same
MRE Magnetic Resonance Elastography	Yes	Yes	Same
Respiratory Navigator	Yes	Yes	Same
NCEMRA Non-Contrast Enhanced Magnetic Resonance Angiography	Yes	Yes	Same
PASS Pair-echo Acquisition of Steady State	Yes	Yes	Same

ITEM	Proposed Device uMR Astra	Predicate Device uMR Ultra (K243547)	Remark
SNAP Simultaneous Non-contrast Angiography and intraPlaque hemorrhage	Yes	Yes	Same
SWI Susceptibility Weighted Imaging	Yes	Yes	Same
SWI+ Susceptibility Weighted Imaging Plus	Yes	Yes	Same
T1rho T1rho Quantitative Mapping Imaging	Yes	Yes	Same
tFAST	Yes	Yes	Same
TRASS Time Reversed Acquisition of Steady State	Yes	Yes	Same
uCS united Compressed Sensing	Yes	Yes	Same
uCSR united Compressed Sensing with Radial Acquisition	Yes	Yes	Same
uFreeR UIH Free Radial imaging	Yes	Yes	Same
uSWIFT Susceptibility Weighted Imaging with Fast Technique	Yes	Yes	Same
UTE Ultra-short Time of Echo	Yes	Yes	Same
WFI Water Fat Imaging	Yes	Yes	Same
QScan	Yes	Yes	Same
Myocardial Perfusion Imaging	Yes	Yes	Same
Cardiac Function	Yes	Yes	Same
Myocardial Tagging	Yes	Yes	Same
Myocardial Mapping	Yes	Yes	Same
MRCA Magnetic Resonance Coronary Angiography	Yes	Yes	Same

ITEM	Proposed Device uMR Astra	Predicate Device uMR Ultra (K243547)	Remark
Silicone-Only Imaging	Yes	Yes	Same
WAVE	Yes	No	Note 6
Workflow			
EasyScan	Yes	Yes	Same
MoCap Motion Capture	Yes	Yes	Same
EasyBolus	Yes	Yes	Same
Auto Bolus Tracker	Yes	Yes	Same
Breast Biopsy	Yes	Yes	Same
Inline CEST	Yes	Yes	Same
TI Scout	Yes	Yes	Same
EasyFACT	Yes	Yes	Same
EasyCrop	Yes	Yes	Same
ImageGuard	Yes	Yes	Same
Inline Stitching	Yes	Yes	Same
Image Reconstruction			
ACS	Yes	Yes	Same
DeepRecon	Yes	Yes	Same
t-ACS	Yes	Yes	Same
AiCo	Yes	Yes	Same
SparkCo	Yes	Yes	Same
Imaging Processing			
Inline Cardiac Function	Yes	Yes	Same
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
Inline ECV	Yes	Yes	Same
Inline MOCO	Yes	Yes	Same
Inline Maps	Yes	Yes	Same
Spectroscopy			
CSI MRS Head	Yes	Yes	Same

ITEM	Proposed Device uMR Astra	Predicate Device uMR Ultra (K243547)	Remark
Chemical Shift Imaging Magnetic Resonance Spectroscopy Head			
CSI MRS Prostate Chemical Shift Imaging Magnetic Resonance Spectroscopy Prostate	Yes	Yes	Same
SVS MRS Head Single-Voxel Spectroscopy Magnetic Resonance Spectroscopy Head	Yes	Yes	Same
SVS MRS Breast Single-Voxel Spectroscopy Magnetic Resonance Spectroscopy Breast	Yes	Yes	Same
SVS MRS Liver Single-Voxel Spectroscopy Magnetic Resonance Spectroscopy Liver	Yes	Yes	Same
SVS MRS Prostate Single-Voxel Spectroscopy Magnetic Resonance Spectroscopy Prostate	Yes	Yes	Same
Other Functions			
EasyRegister	Yes	Yes	Same
Implant Safety Mode	Yes	Yes	Same
uRemote Assistant	Yes	Yes	Same

Note 1	The max gradient amplitude of the proposed device is smaller 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.
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Note 2	The number of receive channels of the proposed device is less than that of the predicate device. The difference did not raise new safety and effectiveness concerns.
Note 3	UHD SuperFlex Neck & Chest - 24 is identical to UHD SuperFlex Free - 24 of the predicate device. The only difference between them is the name of the coil. The difference did not raise new safety and effectiveness concerns.
Note 4	The intended use of UHD Head & Neck Coil - 72 is equivalent to Head & Neck Coil - 48 of the predicate device. 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 5	The intended use of UHD Neuro-Cardiovascular Coil - 96 is equivalent to Head & Neck Coil - 48 of the predicate device. The first difference between them is that the number of channels of the receiver coil. The second difference is that the UHD Neuro-Cardiovascular Coil - 96 is a comprise of UHD Head & Neck Coil - 72 and UHD SuperFlex Neck & Chest -24, both of which can be used alone. The differences did not raise new safety and effectiveness concerns.
Note 6	WAVE is an acceleration technique making full use of the coil sensitivity of the three dimensions by using sinusoidal gy and gz gradients with a $\pi/2$ phase shift between the waveforms to incur a corkscrew trajectory in k-space. The new function did not raise new safety and effectiveness concerns.

Table 3 Comparison to reference device#1

ITEM	Proposed Device uMR Astra	Reference Device#1 uMR Omega (K243122)	Remark
Imaging Features			
MTP MulTiPlex	Yes	Yes	Same
QSM Quantitative Susceptibility Mapping	Yes	Yes	Same

Table 4 Comparison to reference device#2

ITEM	Proposed Device uMR Astra	Reference Device#2 uWS-MR (K220332)	Remark
Image Reconstruction			
Inner View	Yes	Yes	Same
Fusion	Yes	Yes	Same

8. Performance Date

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

Non-Clinical Testing

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

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

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI/AAMIES60601-1: 2005/ (R) 2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012) [IncludingAmendment2(2021)] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-33 Ed. 4.0:2022 Medical Electrical Equipment - Part 2-33: Particular Requirements for The Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnostic
- IEC 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 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.
- IEC /TS 60601-4-2: 2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- 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

Software

- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- NEMA PS 3.1-3.20(2023e): Digital Imaging and Communications in Medicine (DICOM) Set
- 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 10993-11:2017, Edition 3.0, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- 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, EasyBolus, Easy FACT, TI Scout, Inline MOCO, Inline Cardiac Function, Inline ECV, uVision and EasyRegister).
- 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 Ultra system, with the approval number K243547. In addition, we have conducted additional validation on the uMR Astra 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
Image SNR	Calculating NRMSE for both ACS and CS images under the same acceleration factors and protocol parameters	The ratio of error: NRMSE(ACS)/NRMSE(CS) is always less than 1.	Pass
Image Resolution	Calculating SSIM for both ACS and CS images under the same acceleration factors and protocol parameters	The ratio: SSIM(ACS)/SSIM(CS) is always less than 1.	Pass
Image Contrast	Comparing the ROI signal intensities between images acquired with fully sampled and ACS images of same tissues.	Measurements differences on ACS and fully sampled images of same structures under 5% is acceptable.	Pass
Local 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
Performance comparison between uMR Astra and uMR Ultra	PSNR measurements on fully sampled, ACS and CS images on uMR Astra and uMR Ultra	PSNR measurements difference under 5%	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 Ultra system, with the approval number K243547. Validation on the uMR Astra system was conducted with 25 volunteers 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: 321.82	PASS
		DeepRecon: 457.44	
Image uniformity	Uniformity difference between DeepRecon images and NADR images under 5%	0.06%	PASS
Image contrast	Intensity difference between DeepRecon images and NADR images under 5%	0.5%	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.

Summary

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 Astra 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 UIH MRI 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 741 cases from 34 volunteers covering various genders, age groups, ethnicities and BMI groups as shown in the tables below.

Subjects' Characteristics	Total(N=34)
Gender	Number
Male	18
Female	16
Age	
18-28	11
29-40	12
> =41	11
Ethnicity	
White	10
Black	9
Asian	15
BMI	
<= 24.9	14
> 24.9	20

Body part /Phantom	Dynamic MRI scan applications	Number of cases
HEAD	Type I: Non-periodic physiological movement	92
SPINE	Type I: Non-periodic physiological movement	93
HIP	Type I: Non-periodic physiological movement	64
CARDIAC	Type II: Cardiac periodic movement	30
KNEE	Type I: Non-periodic physiological movement	94
ABDOMEN	Type III: Contrast enhancement	65
	Type I: Non-periodic physiological movement	86
PELVIS	Type III: Contrast enhancement	30
	Type I: Non-periodic physiological movement	88
ANKLE	Type I: Non-periodic physiological movement	69
PHANTOM	Type I: Non-periodic physiological movement	30

Equipments and Protocols

The test data were acquired by uMR Astra 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 Astra 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.

The AiCo had already received FDA cleared for the uMR Ultra system, with the approval number K243547. 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 112 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	10
Neck	11
Shoulder	10
Spine	12
Thorax	6
Abdomen	7
Cardiac	6
Pelvis	14
Hip	8
Knee	10
Ankle	10
Upper Extremity	8
Total	112

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.

● SparkCo

SparkCo (Spark artifact Correction) is a feature that can correct the detected spark artifacts and reduce the appearance of spark artifacts for clinical review.

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 for clinical review.

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 below. 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 below.

Subjects' Characteristics	Total(N=15)
Gender	
Male	9
Female	6
Age	
18-29	2
30-44	8
45-64	4
>=65	0
Ethnicity	
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 below 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	1. Based on the simulated spark testing dataset, calculating the PSNR (Peak signal-to-noise ratio) of the spark-corrected images and original spark images 2. Based on the real-world spark dataset, evaluating the image quality improvement between the spark-corrected images and spark images by one experienced evaluator.	1. The average PSNR of spark-corrected images need to be higher than the spark images. 2. Spark artifacts need to be reduced or corrected after enable the SparkCo.	1. The average PSNR of spark-corrected images is 1.6 higher than the spark images. 2. The images with spark artifacts were successfully corrected after enable the SparkCo.

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.

Summary

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
> 41	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.

● 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.

● 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.

● TI Scout

TI Scout is a function that automatically detects the TI frame which has the darkest ventricular myocardium of the TI Scout 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 ED/ES Phases Recognition

Inline ED/ES phases recognition algorithm of the inline cardiac function is used to get the ED and ES Phases based on the automatic left ventricular volume segmentation. The performance testing for inline ED/ES phases recognition algorithm was performed on 95 cases.

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 the 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	0.19
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 Cardiac Function Segmentation

Based on short axis images of the heart, the Inline Cardiac Function Segmentation algorithm is used to segment the left ventricle (LV), right ventricle (RV), and left ventricular myocardium to achieve inline cardiac function.

Acceptance Criteria

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

Validation Type	Acceptance Criteria
Similarity	To evaluate the Inline Cardiac Function Segmentation, we compared the results with those of the cardiac function application of uWS-MR workstation (cleared via K192601).66 test data were used, all of which were scanned well without severe artifacts. Analyze DICE of algorithm segmentation results between two devices to evaluate consistency. If $dice > 0.95$, it is considered consistent between the two.

Testing Data Information

We evaluated 66 cases to validate the algorithm. The distribution is as the following table.

Subjects' Characteristics	Total(N=66)
Gender	Number
Male	12
Female	4
Unknown	50
Age	
18-40	4
> 41	12
Unknown	50
BMI (kg/m(2))	
<18.5	3
[18.5, 25)	20
>=25	37
Unknown	6
Magnetic field strength (T)	

1.5	3
3	10
5	3
Unknown	50
Ethnicity	
Asia	16
White	50
Disease conditions	
Negative	40
Positive	10
Unknown	16

Performance Testing Summary

The test set data validation results are as follows:

sample size of test set	Sample size whose results meet the design requirements	Sample size whose results do not meet the design requirements
66	66	0

Testing & Training Data Independence

The training data used for the training of the Inline Cardiac Function Segmentation algorithm is independent of the data used to test the algorithm.

● Inline ECV

Inline ECV aims to calculate the pixel-wise ECV (extracellular volume fraction) images. We have native and post T1 mapping. In general, the native and post T1 mapping data are aligned. We also provide the registration to keep them aligned. Then we will segment a region in the left ventricle blood pool. Finally, we obtained the ECV images according to the following formula.

$$ECV = (1 - Hct) \times \frac{\frac{1}{T1_{post}} - \frac{1}{T1_{native}}}{\frac{1}{T1_{post_bloodpool}} - \frac{1}{T1_{native_bloodpool}}} \times 100$$

Where, Hct is the Hematocrit, T1post and T1native are the aligned post and native T1 mapping. T1post_bloodpool and T1native_bloodpool are the mean value of blood pool region of the post contrast and native images.

Inline ECV Segmentation

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.

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, 25)	7
>=25	15
Unknown	6
Magnetic field strength (T)	
1.5	13
3	15

Ethnicity	
Asian	17
White	11
Disease conditions	
Negative	19
Postive	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%
Disease conditions				
Negative	100%	0%	0%	100%
Postive	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

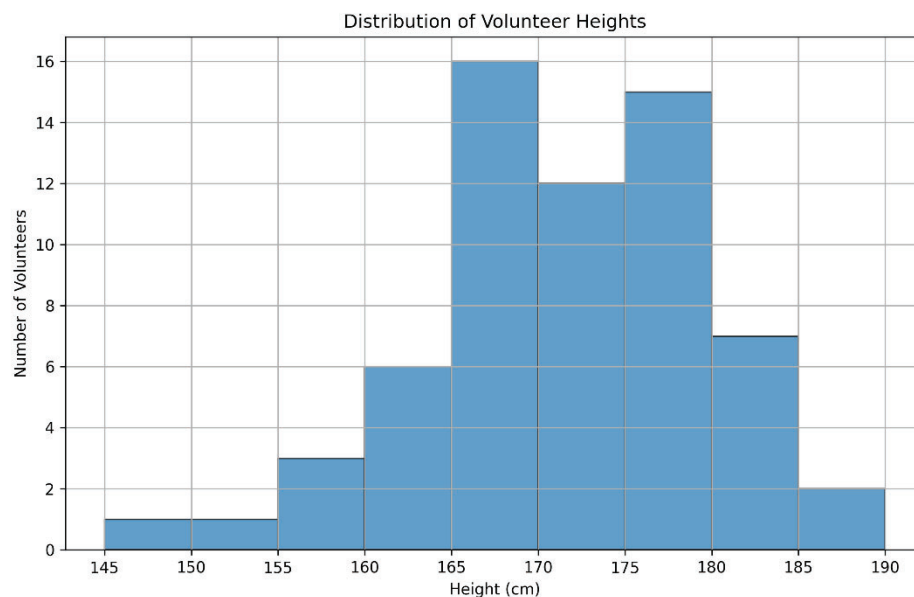
The ground truth for the height data of volunteers is measured by using physical examination standards to determine the height values of each volunteer.

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

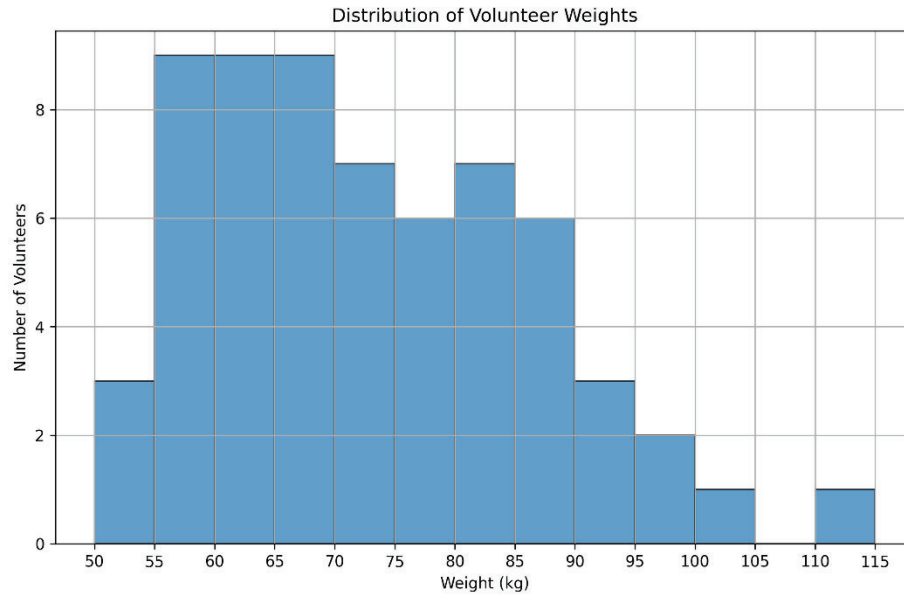
The ground truth for the weight data of volunteers is measured by using physical examination standards to determine the weight values of each volunteer.

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.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uMR Astra 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.