May 21, 2025

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

Re: K243122
Trade/Device Name: uMR Omega
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: April 15, 2025
Received: April 15, 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243122

Device Name

uMR Omega

Indications for Use *(Describe)*

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.

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.

510 (k) SUMMARY

K243122

1. Date of Preparation

April 15, 2025

2. Sponsor Identification

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

Contact Person: Xin GAO
Position: Regulatory Affairs Specialist
Tel: +86-021-67076888-5386
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3. Identification of Proposed Device

Trade Name: uMR Omega
Common Name: Magnetic Resonance Imaging System
Model: uMR Omega

Regulatory Information
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH, MOS
Review Panel: Radiology

4. Identification of Primary/Reference Device(s)

Predicate Device

510(k) Number: K240540, K230152, K220332
Device Name: uMR Omega
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH, MOS
Review Panel: Radiology

Reference Device#1

510(k) Number: K220332
Device Name: uWS-MR
Regulation Name: Medical Image Management and Processing System
Regulatory Class: II
Product Code: LLZ, QIH
Review Panel: Radiology

Reference Device#2

510(k) Number: K234154
Device Name: uPMR 790
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO, MOS
Review Panel: Radiology

5. Device Description

The uMR Omega is a 3.0T superconducting magnetic resonance diagnostic device with a 75cm size patient bore. It consists of components such as magnet, RF power amplifier, RF coils, gradient power amplifier, gradient coils, patient table, spectrometer, computer, equipment cabinets, power distribution system, internal communication system, and vital signal module etc. The uMR Omega Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

This traditional 510(k) is to request modifications for the cleared uMR Omega(K240540). The modifications performed on the uMR Omega in this submission are due to the following changes that include:

(1) Addition of RF coils and corresponding accessories: Breast Coil - 12, Biopsy Configuration, Head Coil - 16, Positioning Couch-top, Coil Support, Tx/Rx Head Coil.
(2) Modification of the mmw component name: from mmw100 to mmw101.
(3) Modification of the dimensions of detachable table: from width 826mm, height 880mm, length 2578mm to width 810mm, height 880mm, length 2505mm.
(4) Addition and modification of pulse sequences:
    a) New sequences: gre_pass, gre_mtp, epi_dti_msh, gre_fsp_c(3D LGE).
    b) Added Associated options for certain sequences: fse(MicroView), fse_mx(MicroView), gre(Output phase image), gre_swi(QSM),

gre_fsp_c(DB/GB PSIR), gre_bssfp(TI Scout), gre_bssfp_ucs(Real Time Cine), epi_dwi(IVIM), epi_dti(DSI, DKI).

c) Added Additional accessory equipment required for certain sequences: gre_bssfp (Virtual ECG Trigger).

d) Added applicable body parts: epi_dwi_msh, gre_fine, fse_mx.

(5) Addition of imaging processing methods: Inline Cardiac function, Inline ECV, Inline MRS, Inline MOCO and MTP.

(6) Addition of workflow features: EasyFACT, TI Scout, EasyCrop, ImageGuard, MoCap and Breast Biopsy.

(7) Addition of image reconstruction methods: SparkCo.

(8) Modification of function: uVision (add Body Part Recognization), EasyScan(add applicable body parts).

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

6. Indications for Use

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.

7. Comparison of Technological Characteristics with the Predicate Device

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

Table 1 Comparison to Predicate device

ITEM	**Proposed Device uMR Omega**	**Predicate Device uMR Omega (K240540, K230152, K220332)**	**Remark**
Magnet system			
Field Strength	3.0 Tesla	3.0 Tesla	Same
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	75 cm	75 cm	Same
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K240540, K230152, K220332)	Remark
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
Gradient system			
Max gradient amplitude	45 mT/m	45 mT/m	Same
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
Number of receive channels	Up to 96	Up to 96	Same
Amplifier peak power per channel	uXD2181: 18 kW uXD2201: 20 kW	uXD2181: 18 kW uXD2201: 20 kW	Same
RF Coils			
Volume Transmit Coil	Yes	Yes	Same
Head & Neck Coil -24	Yes	Yes	Same
Body Array Coil - 12	Yes	Yes	Same
Breast Coil - 10	Yes	Yes	Same
Flex Coil Large - 8	Yes	Yes	Same
Flex Coil Small - 8	Yes	Yes	Same
Knee Coil - 12	Yes	Yes	Same
Lower Extremity Coil - 36	Yes	Yes	Same
Shoulder Coil - 12	Yes	Yes	Same
Small Loop Coil	Yes	Yes	Same
Spine Coil - 32	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
Cardiac Coil - 24	Yes	Yes	Same
Temporomandibular Joint Coil - 4	Yes	Yes	Same
Foot & Ankle Coil - 24	Yes	Yes	Same
Head Coil - 32	Yes	Yes	Same
Head Coil - 12	Yes	Yes	Same
Carotid Coil - 8	Yes	Yes	Same
Infant Coil - 24	Yes	Yes	Same
Body Array Coil - 24	Yes	Yes	Same
Head & Neck Coil - 48	Yes	Yes	Same
Spine Coil - 48	Yes	Yes	Same
Head Coil - 64	Yes	Yes	Same
SuperFlex Body - 24	Yes	Yes	Same

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K240540, K230152, K220332)	Remark
SuperFlex Large - 12	Yes	Yes	Same
SuperFlex Small - 12	Yes	Yes	Same
Tx/Rx Knee Coil - 24	Yes	Yes	Same
SuperFlex Body Wide - 24	Yes	Yes	Same
Breast Coil-24	Yes	Yes	Same
Breast Coil - 12	Yes	No	Note 1
Head Coil - 16	Yes	No	Note 2
Tx/Rx Head Coil	Yes	No	Note 3
Patient table			
Dimensions	Patient Table: width 640mm, height 880mm, length 2620mm Detachable Table: width 810mm, height 880mm, length 2505mm	Patient Table: width 640mm, height 880mm, length 2620mm Detachable Table: width 826mm, height 880mm, length 2578mm	Note 4
Maximum supported patient weight	Patient Table: 310 kg Detachable Table: 310kg	Patient Table: 310 kg Detachable Table: 310kg	Same
Accessories			
Vital Signal Gating	Wireless UIH Gating Unit REF 453564324621 ECG module Ref 989803163121 SpO2 module Ref 989803163111 (alternative)	Wireless UIH Gating Unit REF 453564324621 ECG module Ref 989803163121 SpO2 module Ref 989803163111 (alternative)	Same
	ECG, Rrespiration and pulse module uVWMERP Wireless gating trigger unit uMVRX (alternative)	ECG, Rrespiration and pulse module uVWMERP Wireless gating trigger unit uMVRX (alternative)	Same
	Respiration module mmw101 (optional)	Respiration module mmw100 (optional)	Note 5
Image Processing			
Inline ECV	Yes	No	Note 6
Inline MOCO	Yes	No	Note 7
MTP	Yes	No	Note 8
Workflow			
TI Scout	Yes	No	Note 9
Breast Biopsy	Yes	No	Note 10
uVision	Yes	Yes	Note 11
EasyScan	Yes	Yes	Note 12
Image Reconstruction			

ITEM	Proposed Device uMR Omega	Predicate Device uMR Omega (K240540, K230152, K220332)	Remark
SparkCo	Yes	No	Note 13

Table 2 Comparison to Reference device#1

ITEM	Proposed Device uMR Omega	Reference Device#1 uWS-MR (K220332)	Remark
Image Processing			
Inline Cardiac function	Yes	Yes	Note 14
Inline MRS	Yes	Yes	Note 15

Table 3 Comparison to Reference device#2

ITEM	Proposed Device uMR Omega	Reference Device#2 uPMR 790 (K234154)	Remark
Workflow			
EasyCrop	Yes	Yes	Note 16
ImageGuard	Yes	Yes	Same
Mocap(also named MoCap-Monitoring)	Yes	Yes	Same
EasyFACT(also named Inline FACT)	Yes	Yes	Same

Note 1	The intended use of Breast Coil - 12 is essentially identical to previously cleared Breast Coil - 10. There are two differences between Breast Coil – 12 and Breast Coil – 10. One is that Breast Coil - 12 can be used with Biopsy Configuration to provide breast biopsy function. The other one is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.
Note 2	The intended use of Head Coil - 16 is equivalent to previously cleared Head Coil - 32. The only difference between them is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.
Note 3	The intended use of Tx/Rx Head Coil is essentially identical to previously cleared Head Coil - 12. There are two differences between Tx/Rx Head Coil and Head Coil – 12. One is that Tx/Rx Head Coil is of a 16 Legs High-Pass Birdcage used for transmitter coil. The other one is the number of channels of the receiver coil. The difference did not raise new safety and effectiveness concerns.
Note 4	The dimensions of detachable table were changed from width 826mm, height 880mm, length 2578mm to width 810mm, height 880mm, length 2505mm. The difference did not raise new safety and effectiveness concerns.
Note 5	The model name of mmw component was changed from mmw100 to mmw101. The difference did not raise new safety and effectiveness concerns.
Note 6	Inline ECV aims to calculate the pixel-wise ECV (extracellular volume fraction) images from the native and post T1 mapping. The difference did not raise new safety and effectiveness concerns.
Note 7	Inline MOCO is a function that perform motion correction on MR images, which can reduce the motion caused by physiological factors such as breathing and heart beat in the images. The difference did not raise new safety and effectiveness concerns.

Note 8	MTP is substantially equivalent to GRE and acquires two flip angles and multi-echo images with one scan, and then uses specific image processing to attain multi-parametric images. The difference did not raise new safety and effectiveness concerns.
Note 9	TI Scout automatically selects the TI frame which has the darkest ventricular myocardium of the TI Scout image, allowing users to achieve the best inversion time (TI) and simplifying the workflow which needed the TI. The difference did not raise new safety and effectiveness concerns.
Note 10	Breast Biopsy is a workflow that can provide biopsy instruction for technicians based on the hardware and lesion parameters, the instruction include the biopsy grid coordinate, needle block cell and needle depth. The difference did not raise new safety and effectiveness concerns.
Note 11	During this submission, Body Part Recognition function was included in uVision, which allows assist patient positioning by performing image recognition on human natural images through a 3D camera during the positioning stage. The difference did not raise new safety and effectiveness concerns.
Note 12	EasyScan of the proposed device supports more body parts than that of the predicate device. In this submission, breast and pelvis and hip and ankle and thorax are included. The difference did not raise new safety and effectiveness concerns.
Note 13	SparkCo is an algorithm that can detect and correct spark artifacts (a specific occurring MRI artifact that is caused by electromagnetic interference (EMI)) in MRI images. The difference did not raise new safety and effectiveness concerns.
Note 14	During this submission, inline ED/ES Phases Recognition for Real Time Cine was included in Inline Cardiac function, which allows automatically rearrange the cardiac images into an aligned cardiac cycle. The difference did not raise new safety and effectiveness concerns.
Note 15	Inline MRS of the proposed device are the same as the predicate device. The difference is that the algorithms of Inline MRS are shifted from the post-processing workstation to inline console. The difference did not raise new safety and effectiveness concerns.
Note 16	EasyCrop of the proposed device supports more body parts than that of the predicate device. In this submission, head and carotid and renal are included. The difference did not raise new safety and effectiveness concerns.

8. Performance Data

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

Non-Clinical Testing

Non-clinical testing including surface heating and image performance tests were conducted for the uMR Omega 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 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- IEC 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.
- NEMA MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2-2008(R2020), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 4-2023, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- NEMA MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 6-2008(R2014, R2020), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- NEMA MS 8-2016, Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- NEMA MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- IEC /TR 60601-4-2: 2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software

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

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Biocompatibility

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

Other Standards and Guidance

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

Performance Verification

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

- Performance evaluation report for QSM, MTP, EasyFACT, uVision, TI Scout, Mocap, ImageGuard, SparkCo, EasyCrop, EasyScan, Inline Cardic, Inline ECV, Breast Biopsy and Inline MOCO.
- Sample clinical images for all clinical sequences, coils and imaging processing were reviewed by U.S. board-certified radiologist comparing the proposed device and predicate device. It was shown that the proposed device can generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

Summary of the Machine Learning Algorithm

- ***SparkCo***

SparkCo (Spark artifact Correction) is an algorithm that can detect and correct spark artifacts in MRI images, which will help to restore spark-free image for clinical review when encountering spark artifacts on MRI images.
The spark detection module of SparkCo is based on the AI algorithm, however, it won't change the image directly, and it only provides the K-space location of spark points. Then, the spark correction module based on traditional parallel imaging

reconstruction algorithm will utilize the spark detection results to remove spark points and restore the full-sampled K-space. Through this two-step process, SparkCo can correct spark artifacts and restore the spark-free image.

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

The real-world spark raw data consists of 59 cases collected from 15 patients, serving as the independent testing dataset, which does not overlap with the training dataset. The demographic distribution of this testing dataset is presented in Table 4. And this testing dataset were acquired by using uMR 1.5T and uMR 3T scanners, which cover representative protocols in clinical practice such as T1, T2, and PD with and without fat saturation. Details of acquisition from various body parts are outlined in Table 5.

Table 4. The demographic distribution of real-world spark testing dataset

Subjects' Characteristics (N=15)	**N(%)**
Gender, N(%)	
Male	9(60%)
Female	6(40%)
Age, N(%): Min=18, Max=59, Avg.=30.8, Std.=9.88	
18-29	2(20%)
30-44	8(53.3%)
45-64	4(26.7%)
>=65	0(0.0%)
Ethnicity, N(%)	
White	N.A.
Asian	15(100%)
Body Mass Index (BMI), N(%): Min=17.0, Max=53.5, Avg.=24.0, Std.=7.05	
Underweight (<18.5)	2(13.3%)
Healthy weight (18.5-24.9)	10(66.7%)
Overweight (25.0-29.9)	3(20%)
Obesity (>=30.0)	0(0.0%)

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

Table 5. The various body parts and number of cases included in the real-world spark testing dataset

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

By the test, the SparkCo have been demonstrated with high spark detection accuracy and spark correction effectiveness, as the following Table 6 shows.

Table 6 The test methods and test results of SparkCo

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

In summary, SparkCo meets the criteria for safety and effectiveness, and can used to detect and correct spark artifacts for improving image quality.

- ***Inline ECV***

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

Acceptance Criteria

The validation type and acceptance criteria is shown in the Table 7 below.

Table 7 Validation type and acceptance criteria

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

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 8.

Table 8 Distribution of Patient dataset

Gender	**Number**
Male	20
Female	8
Age	
<18	1
18-28	4
29-40	1
> 41	22
Protocol	
post_t1map_sax	28
native_t1map_sax	28
BMI (kg/m(2))	

<18.5	0
[18.5, 25)	7
>=25	15
Unknown	6
Magnetic field strength (T)	
1.5	13
3	15
Ethnicity	
Asia	17
USA	11
Healthy	
Negative	19
Postive	4
Unknown	5

Performance Testing Summary

According to the subgroup analysis in Table 9, it can be seen that the segmentation algorithm performs as expected in different subgroups.

Table 9 Segmentation algorithm subgroup analysis

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

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.

Summary

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

9. Conclusion

Based on the comparison and analysis above, the proposed device has similar indications for use, performance, safety equivalence, and effectiveness as the predicate device. The differences above between the proposed device and predicate device do not affect the intended use, technology characteristics, safety, and effectiveness. And no issues are raised regarding to safety and effectiveness. The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.