



August 5, 2024

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

Re: K250246
Trade/Device Name: uMR Jupiter
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS, QIH
Dated: July 8, 2025
Received: July 8, 2025

Dear Gao Xin:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ningzhi Digitally
Li -S signed by
Ningzhi Li -S

for

Daniel M. Krainak, Ph.D.

Assistant Director

DHT8C: Division of Radiological

Imaging and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K250246

Device Name

uMR Jupiter

Indications for Use (Describe)

The uMR Jupiter 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 device is intended for patients > 20 kg/44 lbs.

Type of Use (Select one or both, as applicable)



Prescription Use (Part 21 CFR 801 Subpart D)



Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

1. Sponsor Identification

Shanghai United Imaging Healthcare Co., Ltd.

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

Contact Person: Xin GAO

Position: Regulatory Affairs Specialist

Tel: +86-21-67076888-5386

Fax: +86-21-67076889

Email: xin.gao@united-imaging.com

2. Identification of Proposed Device

Trade Name: uMR Jupiter

Common Name: Magnetic Resonance Imaging System

Model: uMR Jupiter

Regulatory Information

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: II

Product Code: LNH, MOS

Secondary Product Code: QIH

Review Panel: Radiology

3. Identification of Primary/Reference Device(s)

Predicate Device

510(k) Number: K233673

Device Name: uMR Jupiter

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: II

Product Code: LNH, MOS

Review Panel: Radiology

Reference Device#1

510(k) Number: K234154

Device Name: uPMR 790

Regulation Name: Emission computed tomography system

Regulatory Class: II

Product Code: OUO, MOS

Review Panel: Radiology

Reference Device#2

510(k) Number: K240540

Device Name: uMR Omega

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: II

Product Code: LNH, MOS

Review Panel: Radiology

4. Device Description

uMR Jupiter is a 5T superconducting magnetic resonance diagnostic device with a 60cm size patient bore and 8 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 Jupiter is designed to conform to NEMA and DICOM standards.

The modification performed on the uMR Jupiter in this submission is due to the following changes that include:

- (1) Addition of RF coils: SuperFlex Large - 24 and Foot & Ankle Coil - 24.
- (2) Addition of applied body part for certain coil: SuperFlex Small-24 (add imaging of ankle).
- (3) Addition and modification of pulse sequences:
 - a) New sequences: fse_wfi, gre_fsp_c (3D), gre_bssfp_ucs, epi_fid(3D), epi_dti_msh.
 - b) Added Associated options for certain sequences: asl_3d (add mPLD) (Only output original images and no quantification images are output), gre_fsp_c (add Cardiac Cine, Cardiac Perfusion, PSIR, Cardiac mapping), gre_quick(add WFI, MRCA), gre_bssfp(add Cardiac Cine, Cardiac mapping), epi_dwi(add IVIM) (Only output original images and no quantification images are output).
- (4) Addition of function: EasyScan, EasyCrop, t-ACS, QScan, tFAST, DeepRecon and WFI.
- (5) Addition of workflow: EasyFACT.

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

5. Indications for Use

The uMR Jupiter 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 device is intended for patients > 20 kg/44 lbs.

6. Comparison of Technological Characteristics with the Predicate Device

uMR Jupiter 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 Jupiter	Predicate Device uMR Jupiter (K233673)	Remark
General			
indications for use	The uMR Jupiter 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.	The uMR Jupiter 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.	Same

ITEM	Proposed Device uMR Jupiter	Predicate Device uMR Jupiter (K233673)	Remark
	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 device is intended for patients > 20 kg/44 lbs.	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 device is intended for patients > 20 kg/44 lbs.	
Magnet system			
Field Strength	5.0 Tesla	5.0 Tesla	Same
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	60 cm	60 cm	Same
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	≤ 1.3 ppm @ 50cm DSV ≤ 0.45 ppm @ 45cm DSV ≤ 0.19 ppm @ 40cm DSV ≤ 0.08 ppm @ 30cm DSV ≤ 0.015 ppm @ 20cm DSV ≤ 0.0009 ppm @ 10cm DSV	≤ 1.3 ppm @ 50cm DSV ≤ 0.45 ppm @ 45cm DSV ≤ 0.19 ppm @ 40cm DSV ≤ 0.08 ppm @ 30cm DSV ≤ 0.015 ppm @ 20cm DSV ≤ 0.0009 ppm @ 10cm DSV	Same
Gradient system			
Max gradient amplitude	120 mT/m	120 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	210.794 MHz	210.794 MHz	Same

ITEM	Proposed Device uMR Jupiter	Predicate Device uMR Jupiter (K233673)	Remark
Number of transmit channels	8	8	Same
Amplifier peak power per channel	8 kW	8 kW	Same
Number of receive channels	96	96	Same
RF Coils			
Volume Transmit Coil	Yes	Yes	Same
SuperFlex Small-24	Yes	Yes	Same
Tx/Rx Head Coil -48	Yes	Yes	Same
Tx/Rx Knee Coil - 24	Yes	Yes	Same
SuperFlex Body - 24	Yes	Yes	Same
Head & Neck Coil - 48	Yes	Yes	Same
Spine Coil - 48	Yes	Yes	Same
SuperFlex Large - 24	Yes	No	Note 1
Patient table			
Dimensions	640 mm×1025 mm×2620 mm	640 mm×1025 mm×2620 mm	Same
Maximum supported patient weight	310 kg	310 kg	Same
Accessories			
Vital Signal Gating	Support ECG/Respiratory/Pulse signal triggering the scan	Support ECG/Respiratory/Pulse signal triggering the scan	Same
Function			
t-ACS	Yes	No	Note 2
EasyFACT	Yes	No	Note 3
tFAST	Yes	No	Note 4

Note 1	The intended use of SuperFlex Large-24 is similar to previously cleared SuperFlex Small-24. There are two differences between them. One is that the size of SuperFlex Large-24 is bigger than SuperFlex Small-24. Another is the applied body parts.
Note 2	t-ACS (temporal AI-assisted Compressed Sensing) is a dynamic magnetic resonance imaging technique which combines traditional Compressed Sensing algorithm with deep learning priors. It outputs multi-phase images. The difference did not raise new safety and effectiveness concerns.
Note 3	Easy FACT is a function which based on the FACT sequence, automatically places the ROI (Regions of Interest) of 5 suitable locations on the liver and performs numerical statistics of quantitative values (FF and R2*), including mean, maximum, minimum and other information, and outputs online reporting. The difference did not raise new safety and effectiveness concerns.
Note 4	tFAST further accelerates acquisition in time dimension on the basis of FAST (Framework for Acceleration STRategy) parallel acceleration technology to improve scanning speed. Suitable for dynamic imaging; It can be used for real-time cardiac imaging and perfusion imaging. The difference did not raise new safety and effectiveness concerns.

Table 2 Comparison to reference device#1

ITEM	Proposed Device uMR Jupiter	Reference Device#1 uPMR 790 (K234154)	Remark
RF Coils			
Foot & Ankle Coil - 24	Yes	Yes	Same
Function			
EasyScan	Yes	Yes	Same
EasyCrop	Yes	Yes	Same
DeepRecon	Yes	Yes	Same
WFI	Yes	Yes	Same

Table 3 Comparison to reference device#2

ITEM	Proposed Device uMR Jupiter	Reference Device#2 uMR Omega (K240540)	Remark
Function			
QScan	Yes	Yes	Same

7. Performance Data

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

Non-Clinical Testing

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

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

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI/AAMIES60601-1: 2005/ (R) 2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012) [Including Amendment 2(2021)] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-33 Ed. 4.0:2022 Medical Electrical Equipment - Part 2-33: Particular Requirements for The Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnostic
- IEC 60825-1: 2014, Edition 3.0, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-6:2010+A1:2013+A2:2020, Edition 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- IEC 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.
- NEMA MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2-2008(R2020), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 4-2023, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices

- NEMA MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 6-2008(R2014, R2020), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- NEMA MS 8-2016, Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- NEMA MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- IEC /TR 60601-4-2: 2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software

- NEMA PS 3.1-3.20(2022d): Digital Imaging and Communications in Medicine (DICOM)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Biocompatibility

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

Other Standards and Guidance

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

Performance Verification

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

- Various testing has been conducted (such as performance testing for WFI, EasyScan, EasyCrop, DeepRecon, t-ACS, Cardiac mapping QScan and EasyFACT).
- 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

● WFI

The WFI (Water-Fat Imaging) is a hybrid water-fat separation algorithm, which utilizes deep learning to improve the stability of conventional algorithms. The framework of WFI is based on the conventional Regional Iterative Phasor Extraction (RIPE) algorithm. Although RIPE has already been widely used for water fat separation in clinical setting, this method is sensitive to phasor initialization and thus subject to water-fat swap artifacts.

To overcome this challenge, an artificial intelligence (AI) network has been trained to provide a more accurate initialization for the RIPE algorithm. To accommodate various clinical needs, WFI provides a user preference setting with three modes (i.e., default mode: conventional RIPE-based WFI, standard mode: hybrid AI-assisted RIPE-based WFI, and fast mode: AI-based WFI).

The training dataset for WFI AI module was collected from 59 volunteers with demographic distributions covering various genders, age groups, and BMI groups (Table 1). Each volunteer was scanned on UIH MRI systems for multiple body parts and WFI imaging protocols, resulted in 2604 cases. In addition, the training dataset covers UIH MRI systems with various magnetic field strengths (1.5T, 3T, and 5T).

Gender	Number
Male	12
Female	47
Age	
18-29	10
30-44	29
45-64	20
Ethnicity	
Asian	59
Body Mass Index (BMI)	

<18.5	1
18.5-24.9	38
25.0-29.9	18
≥30.0	2

For testing of WFI, an independent testing dataset contains 144 cases were collected from 28 volunteers on UIH Jupiter, which is completely separated from the previous mentioned training dataset by collecting from different volunteers and during different time periods. Table 2 shows the demographic distribution of this independent testing dataset, and no clinical subgroups and confounders have been defined for the testing datasets.

Gender	Number
Male	17
Female	11
Age	
18-29	15
30-44	9
45-64	4
Ethnicity	
White	2
Asian	26
Body Mass Index (BMI)	
<18.5	1
18.5-24.9	21
25.0-29.9	4
≥30.0	2

Based on the clinical evaluation of this independent testing dataset by three U.S. certificated radiologists, all three WFI modes meet the requirements for clinical diagnosis. In summary, the WFI performed as intended and passed all performance evaluations.

● 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 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 Jupiter 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 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 dataset of AI module in t-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, resulting in a large number of cases. 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.

The training, validation and test datasets are collected from 76 volunteers, including 41 males and 35 females, ages ranging from 18 to 60. The samples from these volunteers are distributed randomly into training, validation and test datasets.

t-ACS has undergone performance testing on 35 subjects covering various genders, age groups and BMI groups as shown in the table below.

Gender	Number
Male	21
Female	14
Age	
18-28	10
29-40	15
>41	10
Body Mass Index (BMI)	
<24.9	23
>24.9	12
Ethnicity	
White	14
Black	4
Asian	17

Body part / Phantom	Dynamic MRI scan applications	Number of cases
HEAD	Type I: Non-periodic physiological movement	168
SPINE	Type I: Non-periodic physiological movement	94
HIP	Type I: Non-periodic physiological movement	64
KNEE	Type I: Non-periodic physiological movement	94
ABDOMEN	Type II: Contrast enhancement	108
	Type I: Non-periodic physiological movement	30
PELVIS	Type II: Contrast enhancement	28
	Type I: Non-periodic physiological movement	98

ANKLE	Type I: Non-periodic physiological movement	100
PHANTOM	Type I: Non-periodic physiological movement	36

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 t-ACS on uMR Jupiter 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 two applications proved that t-ACS had good agreement with the reference.

● 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 317 volunteers. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols. 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 has undergone performance testing on 20 subjects (2216 cases) with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups.

Gender	Number
Male	10
Female	10
Age	
18-28	5
29-50	9
>50	6
Ethnicity	

White	5
Asian	15
Body Mass Index (BMI)	
< 18.5	2
18.5-24.9	13
> 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.

The DeepRecon has 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. 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.

● EasyFACT

EasyFACT workflow, based on the FACT sequence, automatically places the ROI (Regions of Interest) of 5 suitable locations on the liver and performs numerical statistics of quantitative values (FF and R2*), including mean, maximum, minimum and other information, and outputs online reporting. The 5 ROIs were distributed in certain slice which contains the largest liver lamella, avoiding liver edges and liver vessels. The EasyFACT eliminates the need for users to manually select ROIs and numerical statistics values.

The performance testing for EasyFACT algorithm was performed on 5 subjects during the product development. To verify the effectiveness of the algorithm, the subjective evaluation method was used.

The data were acquired from 5T magnetic resonance imaging equipment from UIH. The data were FACT3d_tra_bh protocol, including Water, Fat, IP, OP, R2Star, FF. The subgroup information of EasyFACT images in testing data is summarized below.

Age	Number
22- 40	1
40- 60	4
Gender	

Female	2
Male	3
Magnetic field strength (T)	
5.0T	5
Ethnicity	
Asia	5

We used the subjective evaluation method to verify the effectiveness of the algorithm. The proposal of algorithm acceptance criteria and score processing are conducted by the licensed physicians with U.S. credentials. The training data used for the training of the EasyFACT algorithm is independent of the data used to test the algorithm.

● 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.

To verify the EasyScan of the algorithm, the subjective evaluation method was used. The EasyScan has undergone performance testing on 30 cases from 18 Asia subjects. In addition, we have conducted validation on the uMR Jupiter system with 40 cases from 8 Asia subjects. The EasyScan has undergone performance testing on various body parts (include head, abdomen, spine, shoulder, cardiac, knee) with diverse demographic distributions covering various genders, age groups.

Gender	Number
Male	7
Female	1
Age	
18-40	3
> 41	5
Magnetic field strength (T)	
5	8
Ethnicity	
Asia	8

The data were acquired from 5T magnetic resonance imaging equipment from UIH. The data consist of easyscout protocols covering various body parts.

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.

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

The pass criteria of EasyScan feature is 99.3%, and the results evaluated by the licenced 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.

- 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.

To verify the EasyCrop of the algorithm, the subjective evaluation method was used. we have conducted validation on the uMR Jupiter system with 5 subjects covering various genders, age groups.

Gender	Number
Male	7
Female	3
Age	
<60	6
≥60	4
Magnetic field strength (T)	
3.0T	5
5.0T	5
Ethnicity	
Asia	10

The data were acquired from 5T magnetic resonance imaging equipment from UIH. The data were Tof3d sequence data.

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.

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 licenced MRI technologist with U.S. credentials. Therefore, EasCrop meets the criteria for safety and effectiveness, and EasCrop can meet the requirements for automatic cropping.

Summary

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

8. Conclusion

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