October 28, 2026

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

Re: K261676
Trade/Device Name: uPMR Zenith
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: OUO, MOS
Dated: September 24, 2026
Received: September 24, 2026

Dear Xin Gao:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81.

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,



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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261676

Please provide the device trade name(s).

uPMR Zenith

Please provide your Indications for Use below.

The uPMR Zenith system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners. This product provides image recognition and image fusion technologies for clinical diagnosis. PET and MR can be scanned simultaneously or separately. This product utilizes the tissue imaging from MR to provide attenuation correction maps for PET studies.
The combined PET/MR system includes the hardware and software necessary for both PET and MR imaging. Its fundamental software functions include image fusion and image stitching.
MR imaging technology is based on the spatial distribution of hydrogen atoms, whereas PET imaging technology relies on the in vivo distribution of radioactive tracers.
This product is intended to assist healthcare professionals, including radiologists and nuclear medicine specialists in detecting, localizing, and diagnosing diseases. In certain scenarios, the use of MR contrast agents may be required.

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)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510 (k) SUMMARY K261676

1. Date of Preparation

September 11, 2026

2. Sponsor Identification

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

Contact Person: Xin GAO
Position: Regulatory Affair Manager
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade Name: uPMR Zenith
Common Name: Positron Emission Tomography and Magnetic Resonance Imaging System
Model: uPMR Zenith

Regulatory Information
Regulation Number: 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO
Second Product Code: MOS
Review Panel: Radiology

4. Identification of Primary/Reference Device(s)

Predicate Device

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#1

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#2

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#3

510(k) Number: K232712
Device Name: uMI Panorama
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

Reference device#4

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#5
510(k) Number: K260113

Device Name: uMR Astra
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Review Panel: Radiology

5. Device Description

The uPMR Zenith system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and iso-centrically. It consists of components such as the PET detector, main magnet, gradient coils and amplifier, radiofrequency (RF) transmit coil and amplifier, spectrometer, RF receive coils, host computer and software, patient table, power system, internal communication system, and vital signal monitor, etc. The MR is intended to produce 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. Contrast agents may be used depending on the region of interest of the scan. The PET provides distribution information of PET radiopharmaceuticals within the human body to assist healthcare providers in assessing the metabolic and physiological functions. uPMR Zenith 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 uPMR Zenith system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners. This product provides image recognition and image fusion technologies for clinical diagnosis. PET and MR can be scanned simultaneously or separately. This product utilizes the tissue imaging from MR to provide attenuation correction maps for PET studies.
The combined PET/MR system includes the hardware and software necessary for both PET and MR imaging. Its fundamental software functions include image fusion and image stitching.
MR imaging technology is based on the spatial distribution of hydrogen atoms, whereas PET imaging technology relies on the in vivo distribution of radioactive tracers.

This product is intended to assist healthcare professionals, including radiologists and nuclear medicine specialists in detecting, localizing, and diagnosing diseases. In certain scenarios, the use of MR contrast agents may be required.

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 uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
Indications for use	The uPMR Zenith system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners. This product provides image recognition and image fusion technologies for clinical diagnosis. PET and MR can be scanned simultaneously or separately. This product utilizes the tissue imaging from MR to provide attenuation correction maps for PET studies. The combined PET/MR system includes the hardware and software necessary for both PET and MR imaging. Its fundamental software functions include image fusion and image stitching. MR imaging technology is based on the spatial distribution of hydrogen atoms, whereas PET imaging technology relies on the in vivo distribution of radioactive tracers. This product is intended to assist healthcare professionals, including radiologists and nuclear medicine specialists in detecting, localizing, and diagnosing diseases. In certain scenarios, the use of MR contrast agents may be required.	The uPMR 790 system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and iso-centrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and/or PET imaging. The MR is intended to produce 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. Contrast agents may be used depending on the region of interest of the scan. The PET provides distribution information of PET radiopharmaceuticals within the human body to assist healthcare providers in assessing the metabolic and physiological functions. The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.	Only the descriptions are different; there is no actual difference.

Table 2 Comparison to Predicate device

ITEM	Proposed Device uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
PET			
Resolution	1 cm: FWMH 2.8 mm±0.4 mm 10 cm: FWHM 3.2 mm±0.4 mm 20 cm: FWHM≤6.0 mm	1 cm: FWMH≤3.2 mm 10 cm: FWHM≤3.6 mm 20 cm: FWHM≤4.8 mm	Note 1
Sensitivity	0 cm: ≥27 cps/kBq 10 cm: ≥27 cps/kBq	0 cm: ≥14 cps/kBq 10 cm: ≥14 cps/kBq	Note 2
Scatter fraction, count losses and randoms measurement	NECR peak: ⩾500 kcps True peak: ≥2500 kcps Scatter Fraction: ≤0.42	NECR peak: ⩾110 kcps True peak: ≥300 kcps Scatter Fraction: ≤0.46	Note 3
Accuracy	maximum value of the bias at or below necr peak activity value:≤5%	maximum value of the bias at or below necr peak activity value:≤10%	Note 4
Image quality	Contrast Recovery coefficient: 10 mm: ≥56.0% 13 mm: ≥61.0% 17 mm: ≥66.0% 22 mm: ≥72.0% 28 mm: ≥76.0% 37 mm: ≥81.0% Noise: 10 mm: ≤7.5% 13 mm: ≤7.0% 17 mm: ≤7.0% 22 mm: ≤7.0% 28 mm: ≤5.0% 37 mm: ≤5.0% Relative lung error:≤8.0%	Contrast Recovery coefficient: 10 mm: ≥45.0% 13 mm: ≥55.0% 17 mm: ≥55.0% 22 mm: ≥65.0% 28 mm: ≥65.0% 37 mm: ≥70.0% Noise: 10 mm: ≤9.0% 13 mm: ≤8.0% 17 mm: ≤7.0% 22 mm: ≤7.0% 28 mm: ≤7.0% 37 mm: ≤7.0% Relative lung error:≤10%	Note 5
Time of Fly (TOF) resolution	≤200 ps	≤560 ps	Note 6
Magnet system			
Field Strength	3.0 Tesla	3.0 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	≤ 2.300 ppm @ 50 cm DSV ≤ 0.800 ppm @ 45cm DSV ≤ 0.380 ppm @ 40 cm DSV	≤ 2.400 ppm @ 50 cm DSV ≤ 0.800 ppm @ 45cm DSV ≤ 0.390 ppm @ 40 cm DSV ≤ 0.110 ppm @ 30 cm DSV ≤ 0.038 ppm @ 20 cm DSV	Note 7

ITEM	Proposed Device uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
	≤ 0.080 ppm @ 30 cm DSV ≤ 0.020 ppm @ 20 cm DSV ≤ 0.002 ppm @ 10 cm DSV	≤ 0.020 ppm @ 10 cm DSV	
Gradient system			
Max gradient amplitude	90 mT/m	45 mT/m	Note 8
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	18 kW	Note 9
Maximum number of receive channels	144	48	Note 10
RF Coils			
Volume Transmit Coil	Yes	Yes	Note 11
Shoulder Coil - 12	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
SuperFlex Large - 12	Yes	Yes	Same
SuperFlex Small - 12	Yes	Yes	Same
SuperFlex Body - 24	Yes	Yes	Same
Infant Coil - 24	Yes	Yes	Same
Small Loop Coil	Yes	Yes	Same
Foot & Ankle Coil - 24	Yes	Yes	Same
Carotid Coil - 8	Yes	Yes	Same
Temporomandibular Joint Coil - 4	Yes	Yes	Same
Accessories			
Head Motion Calibration Camera	Yes	No	Note 12

ITEM	Proposed Device uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
Safety			
Electrical Safety	Comply with ES 60601-1	Comply with ES 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Max SAR for Transmit Coil	Comply with IEC 60601-2-33	Comply with IEC 60601-2-33	Same
Max dB/dt	Comply with IEC 60601-2-33	Comply with IEC 60601-2-33	Same
Biocompatibility	Comply with ISO 10993 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
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

ITEM	Proposed Device uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
DB SWI Dark Blood of Susceptibility Weighted Imaging	Yes	Yes	Same
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
3D MRCP 3D Magnetic Resonance CholangioPancreatography	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
SNAP	Yes	Yes	Same

ITEM	Proposed Device uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
Simultaneous Non-contrast Angiography and intraPlaque hemorrhage			
SWI Susceptibility Weighted Imaging	Yes	Yes	Same
SWI+ Susceptibility Weighted Imaging Plus	Yes	Yes	Same
T1rho T1rho Quantitative Mapping Imaging	Yes	Yes	Same
TRASS Time Reversed Acquisition of Steady State	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
Silicone-Only Imaging	Yes	Yes	Same
Workflow			
ImageGuard	Yes	Yes	Same

ITEM	Proposed Device uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
EasyScan	Yes	Yes	Same
EasyCrop	Yes	Yes	Same
MoCap Motion Capture	Yes	Yes	Same
Image Reconstruction			
ACS	Yes	Yes	Same
DeepRecon	Yes	Yes	Same
uCS	Yes	Yes	Same
HYPER Iterative	Yes	Yes	Same
PET/MR MRAC with Bone Segmentation	Yes	Yes	Same
Digital Gating	Yes	Yes	Same
uExcel DPR	Yes	Yes	Same
Spectroscopy			
CSI MRS Head Chemical Shift Imaging Magnetic Resonance Spectroscopy Head	Yes	Yes	Same
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	Yes	Yes	Same

ITEM	Proposed Device uPMR Zenith	Predicate Device uPMR 790 (K234154)	Remark
Resonance Spectroscopy Prostate			
Other Functions			
Implant Safety Mode	Yes	Yes	Same

Note 1	The spatial resolution at 1 cm and 10cm of the proposed device differs in its expression format (changing from a one-sided interval to a two-sided interval), while the actual specification values remain unchanged. For the 20cm resolution specification, the Depth of Interaction (DOI) effect will lead to radial and tangential degrade according to the point source location and longer axial field-of-view of proposed device (42cm, comparing predicate device 32cm) will increase its axial resolution. The specification of proposed device enlarges the acceptance criterion of 20cm point source resolution results, the actual test result shows proposed device 20cm spatial resolution increase a little than proposed device, and meet the criterion. The 20cm off-center spatial resolution depicts the system geometry design changes, but will not rise new any safety and effectives concerns. In a PET system, increasing the axial field-of-view (axial length) will generally cause the spatial resolution at 20 cm from the center plane to degrade, i.e., the deviation becomes larger. This is mainly due to the increased photon incidence angle and larger depth-of-interaction (DOI) uncertainty at large axial offsets, which worsens the positioning accuracy. Since the proposed device has a longer axial field-of-view (42cm) than the Predicate device (32cm), we have relaxed the spatial resolution specification at 20 cm to account for the increased spatial resolution deviation. However, this does not mean that the typical spatial resolution at 20 cm is degraded. The detailed test report is available for reference. The difference doesn't raise new safety and effectiveness concerns.
Note 2	Sensitivity means the true coincidence events rate in counts per second for a given activity source, the higher the sensitivity, the shorter the scanning time be taken to get the same amount of true coincidence events. The difference doesn't raise new safety and effectiveness concerns.
Note 3	The proposed device provides a higher NECR peak value and Peak True Count Rate than the Predicate device. The higher the NECR Peak Value and Peak True Count Rate, the higher radiation source intensity can be support and the shorter the scanning time be taken to get the same amount of true coincidence events under high radiation source intensity. The proposed device provides a lower PET Scatter Fraction than the Predicate device. The lower the PET Scatter Fraction, means the stronger the ability of the system to eliminate scattering coincidence. The difference doesn't raise new safety and effectiveness concerns.
Note 4	The proposed device provides a better Accuracy than the Predicate device. The lower the maximum value of the bias at or below NECR peak activity value, means PET images quantification will be more accurate at high activity. The difference doesn't raise new safety and effectiveness concerns.
Note 5	The Image Quality of the proposed device is better than that of the Predicate device. The difference doesn't raise new safety and effectiveness concerns.

Note 6	The Time-of-flight Resolution of the proposed device is better than that of the Predicate device. The difference doesn't raise new safety and effectiveness concerns.
Note 7	Magnet Homogeneity of the proposed device is better than that of the predicate device. Magnet homogeneity contributes to image quality. The proposed device with better magnet homogeneity is benefit for image quality. The difference doesn't raise new safety and effectiveness concerns.
Note 8	The max gradient amplitude of the proposed device is larger than that of the predicate device. Peripheral nerve stimulation and cardiac stimulation are controlled according to IEC 60601-2-33. The difference doesn't raise new safety and effectiveness concerns.
Note 9	The peak output power of RFPA of the proposed device is higher than that of the predicate device. The increase of peak output power is to reserve power margin for the magnetic resonance imaging system to better adapt to the scanning of patients with large loads, which is beneficial to the effectiveness of the system. The difference doesn't raise new safety and effectiveness concerns.
Note 10	The number of receive channels of the proposed device is more than that of the predicate device, which enables more receive coils in use. The difference doesn't raise new safety and effectiveness concerns.
Note 11	The intended use and the design principle of Volume Transmit Coil are essentially identical to the predicate device. The main difference is the dimension of the birdcage coil. Specific Absorption Rate (SAR) is controlled according to IEC 60601-2-33. The difference doesn't raise new safety and effectiveness concerns.
Note 12	Compared to the predicate device, the proposed device adds Head Motion Calibration Camera. It enables prospective real-time motion correction to decrease image artifacts. The new component doesn't raise new safety and effectiveness concerns.

Table 3 Comparison to reference device#1

ITEM	Proposed Device uPMR Zenith	Reference Device#1 uMR Ultra (K243547)	Remark
RF Coils			
Head & Neck Coil - 48	Yes	Yes	Same
Spine Coil - 48	Yes	Yes	Same
Shoulder Coil - 24	Yes	Yes	Same
Wrist Coil - 24	Yes	Yes	Same
Head Coil - 16	Yes	Yes	Same
UHD SuperFlex Large - 24	Yes	Yes	Same
UHD SuperFlex Small - 24	Yes	Yes	Same
Tx/Rx Knee Coil - 24	Yes	Yes	Same
Breast Coil - 12	Yes	Yes	Same
Breast Coil - 24	Yes	Yes	Same

ITEM	Proposed Device uPMR Zenith	Reference Device#1 uMR Ultra (K243547)	Remark
SuperFlex Whole Body - 48	Yes	Yes	Same
Head & Neck Agile Coil - 48	Yes	No	Note 1
UHD SuperFlex Neck & Chest - 24	Yes	Yes	Note 2
Patient table			
Maximum supported patient weight	310 kg	310 kg	Same
Accessories			
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 Recognization	Yes	Yes	Same
Hand Gesture Recognization	Yes	Yes	Same
Imaging Features			
MQD MultiQuant Decipher	Yes	Yes	Same
MRE Magnetic Resonance Elastography	Yes	Yes	Same
Workflow			
EasyBolus	Yes	Yes	Same
EasyFACT	Yes	Yes	Same
TI Scout	Yes	Yes	Same
Inline Stitching	Yes	Yes	Same
Auto Bolus Tracker	Yes	Yes	Same
Breast Biopsy	Yes	Yes	Same
Image Reconstruction			
t-ACS	Yes	Yes	Same
AiCo	Yes	Yes	Same

ITEM	Proposed Device uPMR Zenith	Reference Device#1 uMR Ultra (K243547)	Remark
SparkCo	Yes	Yes	Same
bFAST	Yes	Yes	Same
tFAST	Yes	Yes	Same
Inline Maps	Yes	Yes	Same
Imaging Processing			
Inline Cardiac Function	Yes	Yes	Same
Inline ECV	Yes	Yes	Same
Inline MOCO	Yes	Yes	Same
Inline MRS	Yes	Yes	Same
Inline Perfusion	Yes	Yes	Same
Inline DTI	Yes	Yes	Same
Inline BOLD	Yes	Yes	Same
Inline CPR	Yes	Yes	Same
Other Functions			
uRemote Assistant	Yes	Yes	Same

Note 1	The intended use of Head & Neck Agile Coil - 48 is equivalent to previously cleared Head & Neck Coil - 48 of the reference device#1. The material density of Head & Neck Agile Coil - 48 is lower to reduce photon attenuation and improve the PET image quality. The difference doesn't raise new safety and effectiveness concerns.
Note 2	UHD SuperFlex Neck & Chest - 24 is identical to UHD SuperFlex Free - 24 of the reference device#1. The only difference between them is the name of the coil. The difference doesn't raise new safety and effectiveness concerns.

Table 4 Comparison to reference device#2

ITEM	Proposed Device uPMR Zenith	Reference Device#2 uMR Omega (K243122)	Remark
Accessories			
Vital Signal Monitor	ECG, Rrespiration and pulse module uVWMERP Wireless gating trigger unit uMVRX	ECG, Rrespiration and pulse module uVWMERP Wireless gating trigger unit uMVRX	Same
	Respiration module	Respiration module	Same

ITEM	Proposed Device uPMR Zenith	Reference Device#2 uMR Omega (K243122)	Remark
	mmw100 (optional)	mmw100 (optional)	
	Wireless CR Module uCORDM (optional)	/	Note 1
Imaging Features			
MTP	Yes	Yes	Same
QSM	Yes	Yes	Same
Workflow			
Inline CEST	Yes	Yes	Same
Spectroscopy			
uWS-MR MRS	Yes	Yes	Same

Note 1	Compared to the predicate device, the proposed device adds Wireless CR Module, which is a non-contact cardiac gating trigger unit based on the Doppler radar detection principle. Compared to contact-based ECG, uCORDM not only simplifies the pre-Scan preparation process but also avoids skin irritancy caused by electrode attachment on the patient. uCORDM can stably achieve cardiac gating trigger functionality. The new component doesn't raise new safety and effectiveness concerns.

Table 5 Comparison to reference device#3

ITEM	Proposed Device uPMR Zenith	Reference Device#3 uMI Panorama (K232712)	Remark
Imaging Processing			
uExcel Unity	Yes	Yes	Same
Workflow			
uExcel iQC	Yes	Yes	Same

Table 6 Comparison to reference device#4

ITEM	Proposed Device uPMR Zenith	Reference Device#4 uWS-MR (K220332)	Remark
Image Reconstruction			
Inner View	Yes	Yes	Same
Fusion	Yes	Yes	Same

Table 7 Comparison to reference device#5

ITEM	Proposed Device uPMR Zenith	Reference Device#5 uMR Astra (K260113)	Remark
RF Coils			
UHD Head & Neck Coil - 72	Yes	Yes	Same
Imaging Features			
WAVE	Yes	Yes	Same

8. Performance Date

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

Non-Clinical Testing

Non-clinical testing including image performance tests were conducted for uPMR Zenith 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 10-2010, Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging
- 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(2024e): 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, uExcel DPR and PET/MR MRAC with Bone Segmentation).
- 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). ACS has been already cleared on the uMR Ultra system, with the approval number K243547.

Fully-sampled k-space data were collected and transformed to image space as the ground-truth. 1102 samples provided by 32 volunteers used for validation on multiple 3T system (including uPMR Zenith) with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups. Clinical protocols varioued contrast such as T1, T2, T1Flair, T2Flair, PD, STIR, etc.

The gold standard data used for training AI networks of ACS is the image corresponding to fully sampled k-space data. The testing data have no overlap with the training data and are completely independent.

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, 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 DeepRecon had been already cleared on the uMR Ultra system, with the approval number K243547. Nearly 4000 cases provided by 36 volunteers were used for validation on multiple 3T system (including uPMR Zenith) with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups. Clinical protocols varioued contrast such as T1, T2, T1Flair, T2Flair, PD, STIR, etc.

In terms of the ground truth in training dataset, the multiple-averaged images with high-resolution and high SNR were collected as the ground-truth images. The testing data had no overlap with the training data and were completely independent. The DeepRecon had been validated to provide image de-nosing 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.

- **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. EasyScan has been already cleared on the uMR Ultra system, with the approval number K243547.

The EasyScan has undergone performance testing on 482 cases from 129 patients with diverse demographic distributions covering various genders, age groups and ethnicities. The data were acquired from 1.5T and 3T magnetic resonance imaging equipment from UIH. The data were easyscout data.

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%.
The testing data is entirely independent and does not share any overlap with the training data.
In 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. t-ACS has been already cleared on the uMR Ultra system, with the approval number K243547.
Fully-sampled k-space data were collected and transformed into image domain as reference. 1265 samples provided by 75 volunteers used for validation on multiple 3T system (including uPMR Zenith) with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI-groups. Clinical protocols varioued contrast such as T1, T2, T1Flair, T2Flair, PD, STIR, etc.
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 testing data have no overlap with the training data and are completely independent.
All 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.

- **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. The AiCo had been already cleared on the uMR Ultra system, with the approval number K243547.

AiCo has undergone performance evaluation on 30 healthy volunteers. Each volunteer was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulting in 177 samples, which cover representative protocols in clinical practice such as T1, T2, PD with and without fat saturation.

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. The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods.

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 designed to detect and correct spark artifacts and reduce their appearance in images used for clinical review. Its detection module uses AI-based classification and segmentation algorithms to identify spark-corrupted locations in k-space. Based on the detection results, a conventional parallel-imaging reconstruction algorithm reconstructs the corrected k-space data. SparkCo had been already cleared on the uMR Ultra system, with the approval number K243547.

The independent real-world test dataset comprised 106 cases from 27 subjects, with manually annotated spark-point locations serving as the reference standard. The subjects represented different sexes, ages, ethnicities, and BMI categories. Data were acquired using UIH 1.5T and 3T MRI systems with representative clinical protocols such as T1, T2 and PD with and without fast saturation.

An independent simulated test dataset included 159 spark-containing slices. Neither test dataset overlapped with the training data.
On the real-world test dataset, SparkCo achieved an average spark-detection accuracy of 94%, exceeding the acceptance criterion of 90%. Image review showed reduced spark artifacts after correction. PSNR and SSIM comparisons based on matched image triplets also indicated improved image fidelity and structural similarity after SparkCo correction. Overall, the results support the safety and performance of SparkCo for its intended use.

- **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. The ImageGuard has been already cleared on the uMR Ultra system, with the approval number K243547.
The ImageGuard has undergone performance testing with 202 cases from 85 subjects with diverse demographic distributions covering various genders, age groups and ethnicities. 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.
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%.
The testing data is entirely independent and does not share any overlap with the training data.
In 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. EasyCrop has been already cleared on the uMR Ultra system, with the approval number K243547.
The EasyCrop has undergone performance testing on 138 cases from 74 patients with diverse demographic distributions covering various genders, age groups and ethnicities. The data were acquired from 1.5T and 3T magnetic resonance imaging equipment from UIH. The data were FSE and GRE sequence data.
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%.
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. The EasyBolus has been already cleared on the uMR Ultra system, with the approval number K243547.
The EasyBolus has undergone performance testing on 20 subjects, with diverse demographic distributions covering various genders, age groups. The data were acquired from UIH 3T magnetic resonance imaging equipment. The data were neck_easy_scout and BolusTracker data.
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.

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

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.

The evaluation results for EasyBolus are carried out by certified professionals in the United States. The testing data is entirely independent and does not share any overlap with the training data.

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

- **EasyFACT**

EasyFACT workflow, based on the gre_fact sequence, automatically places up to 5 ROIs (Regions of Interest) within the liver region of the image. The function has been already cleared on the uMR Ultra system, with the approval number K243547.

A total of 25 cases from 25 volunteers were used for validation (one case per volunteer). Subgroup analysis was performed across gender, age, ethnicity and weight. The algorithm is based on the gre_fact sequence collected from 1.5T, 3.0T and 5.0T MR equipment.

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

The reference standard was based on subjective expert evaluation. ROI placement was judged against three criteria: Satisfied (S) — five ROIs placed within liver parenchyma, avoiding borders and vascular structures; Acceptable (A) — fewer than five ROIs correctly placed; Failure (F) — ROIs on liver borders/vessels or no ROIs placed. The EasyFACT workflow achieved a 100% satisfied and acceptable (S+A)

ratio across all 25 test cases, exceeding the required acceptance threshold of 95%. All cases were rated "Satisfied" (five ROIs correctly placed within liver parenchyma), with zero "Acceptable" or "Failure" outcomes recorded.

- **TI Scout**

TI Scout is a workflow 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). The function has been already cleared on the uMR Ultra system, with the approval number K243547.

A total of 27 cases from 27 volunteers were used for validation (one case per volunteer). Subgroup analysis was performed across gender, age, BMI, magnetic field strength and ethnicity. The algorithm is based on the TIscout_sax sequence collected from 1.5T, 3.0T MR equipment.

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

The gold standard frame was operated and confirmed by an American MRI technologist. The acceptance criteria are 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. The test results of the 27 patients are an average frame difference of 0.37 and a maximum frame difference of 2 frames, which meets the expected passing criteria for the test.

- **Inline MOCO**

Inline MOCO is a function that performs motion correction on MR images, which can reduce the motion caused by physiological factors such as breathing and heartbeat in the images. The function has been already cleared on the uMR Ultra system, with the approval number K243547.

Two datasets were used for validation:

(1) Cardiac Perfusion Images — 105 cases from 60 patients (multiple cases per patient due to different slice locations), with subgroup analysis across age, gender, ethnicity, BMI, magnetic field strength, and disease conditions.

(2) Cardiac Dark Blood Images — 182 cases from 33 patients (multiple cases per patient due to different slice locations), with subgroup analysis across the same categories.

For cardiac perfusion images, data were acquired using T1-weighted sequence from 1.5T and 3T MR equipment. For cardiac dark blood images, data were acquired using FSE sequence from 1.5T and 3T MR equipment.

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

The reference standard (ground truth) was left ventricular myocardium masks labeled by a trained annotator and then reviewed and confirmed by experts. The acceptance criterion is: the average Dice coefficient of the left ventricular myocardium after motion correction must be greater than 0.87. For cardiac perfusion images, the average Dice coefficient after motion correction is 0.92, exceeding the required threshold of 0.87. For cardiac dark blood images, the average Dice coefficient after motion correction is 0.96, also exceeding the threshold of 0.87.

- **Inline Cardiac Function**

When performing the cardiac cine, select Inline Cardiac Function to automatically output the analysis results related to cardiac function (such as parameter tables, volume curves, ED contour segmentation, and ES contour segmentation) after scanning. The function has been already cleared on the uMR Ultra system, with the approval number K243547.

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.

A total of 95 cases from 56 volunteers were used for validation. Subgroup analysis was performed across gender, age, magnetic field strength, disease conditions and ethnicity. The algorithm is based on the gre_bssfp sequence collected from 1.5T, 3.0T MR equipment. The training data used for the training of TI Scout is independent of the data used to test the algorithm.

The ED and ES gold standard indices were evaluated by 3 licensed physicians with U.S. credentials. 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 acceptance criteria are the average error does not exceed 1 frame. The performance testing for Inline ED/ES phases recognition algorithm was performed on 95 cases, with 0.13 average frames error.

Inline Cardiac Function Segmentation

Inline Cardiac Function Segmentation, based on short-axis cardiac images, automatically segments the left ventricle (LV), right ventricle (RV), and left ventricular myocardium within cardiac imaging.

A total of 66 patient cases were used for validation. Subgroup analysis was performed across gender, age, BMI, magnetic field strength, ethnicity and disease status. The algorithm is based on cardiac short-axis images acquired from 1.5T, 3.0T and 5.0T MR equipment. The training data used for Inline Cardiac Function Segmentation is independent of the data used to test the algorithm.

The reference standard was based on segmentation results from the FDA-cleared uWS-MR workstation, where a DICE coefficient > 0.95 serves as the consistency

acceptance threshold. The Inline Cardiac Function Segmentation workflow achieved a 100% consistent ratio across all 66 test cases, exceeding the required acceptance threshold of 95%. All cases met the DICE > 0.95 criterion, with zero non-compliant outcomes recorded. The reference standard was based on segmentation results from the FDA-cleared uWS-MR workstation, where a DICE coefficient > 0.95 serves as the consistency acceptance threshold. The Inline Cardiac Function Segmentation algorithm achieved a 100% consistent ratio across all 66 test cases, exceeding the required acceptance threshold of 95%. All cases met the DICE > 0.95 criterion, with zero non-compliant outcomes recorded.

- **Inline ECV**

Inline ECV aims to calculate the pixel-wise ECV (extracellular volume fraction) images. First, registration is applied to the native and post T1mapping. Next, segment the left ventricular blood pool region. Finally, calculate the ECV image according to the ECV formula. The function has been already cleared on the uMR Ultra system, with the approval number K243547.
A total of 90 cases from 28 patients (multiple cases per patient: native and post T1 mapping; different slice location) were used for validation. Subgroup analysis was performed across gender, age, BMI, magnetic field strength, ethnicity, and disease conditions. The algorithm is based on the native and post T1mapping sequence collected from 1.5T and 3.0T MR equipment.
The training data used for the training of Inline ECV is independent of the data used to test the algorithm.
The reference standard of the Inline ECV segmentation algorithm was based on subjective expert evaluation. Segmentation results were judged against three criteria: 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) — 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.; Failure (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. The Inline ECV segmentation algorithm achieved a 100% satisfaction rate across all 90 test cases, with zero "Acceptable" or "Failure" outcomes recorded, exceeding the required acceptance threshold (no failure cases; satisfaction rate S/(S+A+F) > 95%).

- **uExcel DPR**

uExcel DPR (Deep Progressive Reconstruction) is a deep learning-based PET reconstruction algorithm. It utilizes pre-trained deep neural networks on long-axis datasets to optimize the iterative reconstruction process, effectively reducing noise

and improving contrast. In comparison to the conventional OSEM algorithm, uExcel DPR achieves a higher signal-to-noise ratio in generated images. uExcel DPR has been already cleared on the uPMR 790 system, with the approval number K234154.
The AI model used for DPR reconstruction was trained and tested on data covering a wide range of age groups (19-82 years) and BMI values (16-55). The validation dataset for uExcel DPR was collected from uPMR Zenith, comprising a NEMA IQ phantom data and a clinical dataset of 70 human study. The NEMA IQ phantom scans were performed in compliance with NEMA NU 2-2018 standards. Whole-body imaging protocols were applied for human subject, with total scan durations of 9 minutes over 3 bed positions.
The test data are entirely independent from the training data.
The acceptance criteria for performance testing are: a) for NEMA IQ phantom, the averaged CR, BV, and CNR of the uExcel DPR images should be superior to those of the OSEM images; and b) for human images, uExcel DPR demonstrate superior image SNR compared to OSEM reconstruction.
Benchmark testing demonstrated that uExcel DPR surpasses the conventional OSEM algorithm in the following areas:

1) NEMA IQ Phantom Analysis: Superior noise reduction and CNR improvement;
2) Human subject evaluations: Superior image SNR.

- **PET/MR MRAC with Bone Segmentation**

MRAC with Bone Segmentation is an AI based whole body bone segmentation method on images from Dixon Water Fat Imaging (WFI) sequence. With predefined attenuation factor, the method could generate bone part in the uMap. By infusing prior anatomical knowledge from deep learning with MR acquisition and reconstruction, the demand for dedicated bone-sensitive sequences can be significantly reduced. Much less data is required to produce high-precision bone masks that closely match ground-truth CT-based segmentation. MRAC with Bone Segmentation has been already cleared on the uPMR 790 system, with the approval number K234154.
The bone segmentation has been extended to whole body bone parts.
The algorithm has undergone performance test with 32 cases acquired with uPMR Zenith system, with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups. For each case, the MR WFI image series cover region at least from head to thigh, and for 24 cases, ACCT series was acquired with PET/CT system.
Two acceptance criteria were set for the algorithm test, the first one is the MRAC with bone Segmentation is quantitatively superior to the traditional 4-compartment model (without bone), and the other one is that the quantitative difference between

the average SUV of each organ between MRAC with bone and the CTAC is less than 10%.

The test data are entirely independent from the training data.

The test result shows that for all cases, the MRAC with body bone are quantitatively superior than the traditional 4-compartment model (without bone), and at the whole-body level, the difference of organ SUV is no larger than 6.1% compare to CTAC. And the results evaluated by licensed nuclear medicine physicians with Chinese credentials. Therefore, WFI based whole-body MRAC meets the criteria for safety and effectiveness.

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.