May 24, 2024

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

Re: K234154
Trade/Device Name: uPMR 790
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: OUO, MOS
Dated: April 30, 2024
Received: April 30, 2024

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.

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.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

Submission Number *(if known)*

K234154

Device Name

uPMR 790

Indications for Use *(Describe)*

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.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

Shanghai United Imaging Healthcare Co., Ltd.
Tel: +86 (21) 67076888 Fax: +86 (21) 67076889
www.united-imaging.com

# 510 (k) SUMMARY

## 1. Date of Preparation

December 28, 2023

## 2. Sponsor Identification

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

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

## 3. Identification of Proposed Device

**Trade Name:** uPMR 790
**Common Name:** Positron Emission Tomography and Magnetic Resonance Imaging System
**Model:** uPMR 790

**Regulatory Information**
**Regulation Number:** 21 CFR 892.1200
**Regulation Name:** Emission computed tomography system
**Regulatory Class:** II
**Product Code:** OUO, MOS
**Review Panel:** Radiology

## 4. Identification of Primary/Reference Device(s)

**Predicate Device**

**510(k) Number:** K222540
**Device Name:** uPMR 790
**Regulation Name:** Emission Computed Tomography System
**Regulatory Class:** II
**Product Code:** OUO
**Review Panel:** Radiology

**Reference Device#1**

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

**Reference Device#2**

**510(k) Number:** K210001
**Device Name:** HYPER AiR
**Regulation Name:** Emission computed tomography system
**Regulatory Class:** II
**Product Code:** KPS
**Review Panel:** Radiology

**Reference Device#3**

**510(k) Number:** K193241
**Device Name:** uMI 550
**Regulation Name:** Emission computed tomography system
**Regulatory Class:** II
**Product Code:** KPS, JAK
**Review Panel:** Radiology

## 5. Device Description

The uPMR 790 system is a combined Magnetic Resonance Diagnostic Device (MRDD) and Positron Emission Tomography (PET) scanner. It consists of components such as PET detector, 3.0T superconducting magnet, RF power amplifier, RF coils, gradient power amplifier, gradient coils, patient table, spectrometer, computer, equipment cabinets, power distribution system, internal communication system, vital signal module, and software etc.

The uPMR 790 system provides simultaneous acquisition of high resolution metabolic and anatomic information from PET and MR. PET detectors are integrated into the MR bore for simultaneous, precisely aligned whole body MR and PET acquisition. The PET subsystem supports Time of Flight (ToF). The system software is used for

patient management, data management, scan control, image reconstruction, and image archive. The uPMR 790 system is designed to conform to NEMA and DICOM standards.

This traditional 510(k) is to request modifications for the cleared uPMR 790(K222540). The modifications performed on the uPMR 790 (K222540) in this submission are due to the following changes that include:

(1) Addition of RF coils: SuperFlex Body - 24, SuperFlex Large -12, SuperFlex Small -12.
(2) Addition and modification of pulse sequences:
    (a) New sequences: gre_fine, fse_arms_dwi, fse_dwi, fse_mars_sle, grase, gre_bssfp_ucs, gre_fq, gre_pass, gre_quick_4dncemra, gre_snap, gre_trass, gre_rufis, epi_dwi_msh, svs_wfs, svs_stme.
    (b) Added Associated options for certain sequences: QScan, MultiBand, Silicon-Only Imaging, MoCap-Monitoring, T1rho, CEST, Inline T2 mapping, CASS, inline FACT, uCSR, FSP+, whole heart coronary angiography imaging, mPLD (Only output original control/labeling images and PDw(Proton Density weighted) images, no quantification images are output).
    (c) Name change of certain sequences: gre_ute(old name: gre_ute_sp), svs_press(old name: press),svs_steam(old name: steam), csi_press(old name: press), csi_hise(old name: hise).
(3) Addition of MR imaging processing methods: 2D Flow, 4D Flow, SNAP, CEST, T1rho, FSP+, CASS, PASS, Inline T2 Mapping and DeepRecon.
(4) Addition and modification of PET imaging processing methods:
    (a) The new PET imaging processing methods: Hyper DPR (also named HYPER AiR) and Digital Gating (also named Self Gating).
    (b) The modified method: HYPER Iterative.
(5) Addition of MR image reconstruction methods: AI-assisted Compressed Sensing (ACS).
(6) Addition and modification of workflow features:
    (a) The new workflow features: EasyCrop, MoCap-Monitoring and QGuard-Imaging.
    (b) The modified workflow feature: EasyScan.
(7) Addition Spectroscopy: Liver Spectroscopy, Breast Spectroscopy.
(8) Additional function: MR conditional implant mode.

## 6. Indications for Use

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.

## 7. Comparison of Technological Characteristics with the Predicate Device

uPMR 790 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 devices is provided as below.

Table 1 Comparison to Predicate device

| ITEM | Proposed Device uPMR 790 | Predicate Device uPMR 790(K222540) | Remark |
|---|---|---|---|
| **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 | ≤ 2.400 ppm @ 50 cm DSV<br>≤ 0.800 ppm @ 45cm DSV<br>≤ 0.390 ppm @ 40 cm DSV<br>≤ 0.110 ppm @ 30 cm DSV<br>≤ 0.038 ppm @ 20 cm DSV<br>≤ 0.020 ppm @ 10 cm DSV | ≤ 2.400 ppm @ 50 cm DSV<br>≤ 0.800 ppm @ 45cm DSV<br>≤ 0.390 ppm @ 40 cm DSV<br>≤ 0.110 ppm @ 30 cm DSV<br>≤ 0.038 ppm @ 20 cm DSV<br>≤ 0.020 ppm @ 10 cm DSV | Same |
| **Gradient system** | | | |
| Max gradient amplitude | 45 mT/m | 45 mT/m | Same |
| Max slew rate | 200 T/m/s | 200 T/m/s | Same |
| Shielding | active | active | Same |
| Cooling | water | water | Same |
| **RF system** | | | |
| Resonant frequencies | 128.23 MHz | 128.23 MHz | Same |
| Number of transmit channels | 2 | 2 | Same |

| | | | |
|---|---|---|---|
| Number of receive channels | 48 | 48 | Same |
| Amplifier peak power per channel | 18 kW | 18 kW | Same |
| **RF Coils** | | | |
| Volume Transmit Coil | Yes | Yes | Same |
| Head & Neck Coil - 24 | Yes | Yes | Same |
| Body Array Coil - 12 | Yes | Yes | Same |
| Breast Coil - 10 | Yes | Yes | Same |
| Flex Coil Large - 8 | Yes | Yes | Same |
| Flex Coil Small - 8 | Yes | Yes | Same |
| Knee Coil - 12 | Yes | Yes | Same |
| Lower Extremity Coil - 36 | Yes | Yes | Same |
| Shoulder Coil - 12 | Yes | Yes | Same |
| Small Loop Coil | Yes | Yes | Same |
| Spine Coil - 32 | Yes | Yes | Same |
| Wrist Coil - 12 | Yes | Yes | Same |
| Head Coil - 32 | Yes | Yes | Same |
| Foot & Ankle Coil - 24 | Yes | Yes | Same |
| Cardiac Coil - 24 | Yes | Yes | Same |
| Temporomandibular Joint Coil - 4 | Yes | Yes | Same |
| Carotid Coil - 8 | Yes | Yes | Same |
| Infant Coil - 24 | Yes | Yes | Same |
| **Patient table** | | | |
| Dimensions | W×H×L: 640 mm×890 mm× 2620 mm | W×H×L: 640 mm×890 mm × 2620 mm | Same |
| Maximum supported patient weight | 250 kg | 250 kg | Same |
| **Accessories** | | | |
| Vital Signal Gating | Wireless UIH Gating Unit<br>REF 453564324621<br>ECG module Ref 989803163121<br>SpO2 module Ref 989803163111<br>(alternative) | Wireless UIH Gating Unit<br>REF 453564324621<br>ECG module Ref 989803163121<br>SpO2 module Ref 989803163111<br>(alternative) | Same |
| | uVWMERP<br>uMVRX<br>(alternative) | uVWMERP<br>uMVRX<br>(alternative) | |
| **PET** | | | |
| Resolution | 1 cm: FWMH≤3.2 mm<br>10 cm: FWHM≤3.6 mm<br>20 cm: FWHM≤4.8 mm | 1 cm: FWMH≤3.2 mm<br>10 cm: FWHM≤3.6 mm<br>20cm: FWHM≤4.8 mm | Same |

| | | | |
|---|---|---|---|
| Sensitivity | 0 cm: ≥14 cps/kBq<br>10 cm: ≥14 cps/kBq | 0 cm: ≥14 cps/kBq<br>10 cm: ≥14 cps/kBq | Same |
| Scatter fraction, count losses and randoms measurement | NECR peak:≥110 kcps<br>True peak: ≥300 kcps<br>Scatter Fraction: ≤0.46 | NECR peak:≥110 kcps<br>True peak: ≥300 kcps<br>Scatter Fraction: ≤0.46 | Same |
| Accuracy | maximum value of the bias at or below necr peak activity value:≤10% | maximum value of the bias at or below necr peak activity value:≤10% | Same |
| Image quality | Contrast Recovery coefficient:<br>10 mm: ≥45.0%<br>13 mm: ≥55.0%<br>17 mm: ≥55.0%<br>22 mm: ≥65.0%<br>28 mm: ≥65.0%<br>37 mm: ≥70.0%<br>Noise:<br>10 mm: ≤9.0%<br>13 mm: ≤8.0%<br>17 mm: ≤7.0%<br>22 mm: ≤7.0%<br>28 mm: ≤7.0%<br>37 mm: ≤7.0%<br>Relative lung error:≤10% | Contrast Recovery coefficient:<br>10 mm: ≥45.0%<br>13 mm: ≥55.0%<br>17 mm: ≥65.0%<br>22 mm: ≥65.0%<br>28 mm: ≥65.0%<br>37 mm: ≥70.0%<br>Noise:<br>10 mm: ≤9.0%<br>13 mm: ≤8.0%<br>17 mm: ≤7.0%<br>22 mm: ≤7.0%<br>28 mm: ≤7.0%<br>37 mm: ≤7.0%<br>Relative lung error:≤10% | Note 1 |
| Time of Fly(TOF) resolution | ≤560 ps | ≤560 ps | Same |
| **MR Image Processing Features** | | | |
| CASS | Yes | No | Note 2 |
| PASS | Yes | No | Note 3 |
| HYPER Iterative | Yes | Yes | Note 4 |
| **Workflow Features** | | | |
| EasyScan | Yes | Yes | Note 5 |
| QGuard-Imaging | Yes | No | Note 6 |
| EasyCrop | Yes | No | Note 7 |
| Mocap-Monitoring | Yes | No | Note 8 |

Table 2 Comparison to Reference device#1

| ITEM | Proposed Device uPMR 790 | uMR Omega(K220332) | Remark |
|---|---|---|---|
| SuperFlex Body - 24 | Yes | Yes | Same |
| SuperFlex Large - 12 | Yes | Yes | Same |
| SuperFlex Small - 12 | Yes | Yes | Same |
| **MR Image Processing Features** | | | |
| 2D Flow | Yes | Yes | Same |
| DeepRecon | Yes | Yes | Same |
| Inline T2 Mapping | Yes | Yes | Same |

| | | | |
|---|---|---|---|
| **Spectroscopy Features** | | | |
| Liver Spectroscopy | Yes | Yes | Same |
| Breast Spectroscopy | Yes | Yes | Same |
| **MR Image Reconstruction Features** | | | |
| ACS | Yes | Yes | Same |
| **Function** | | | |
| MR conditional implant mode | Yes | Yes | Same |
| **ITEM** | **Proposed Device uPMR 790** | **uMR Omega(K230152)** | **Remark** |
| **MR Image Processing Features** | | | |
| 4D Flow | Yes | Yes | Same |
| SNAP | Yes | Yes | Same |
| CEST | Yes | Yes | Same |
| T1rho | Yes | Yes | Same |
| FSP+ | Yes | Yes | Same |

Table 3 Comparison to Reference device#2

| ITEM | Proposed Device uPMR 790 | Reference Device#2 HYPER AiR(K210001) | Remark |
|---|---|---|---|
| HYPER DPR | Yes | Yes | Same |

Table 4 Comparison to Reference device#3

| ITEM | Proposed Device uPMR 790 | Reference Device#3 uMI 550(K193241) | Remark |
|---|---|---|---|
| Digital Gating | Yes | Yes | Same |

| | |
|---|---|
| Note 1 | The contrast recovery coefficient of 17mm spheres is updated from 55% to 65%, while historical test data shows the test results can meet 65% requirement.<br>The difference did not raise new safety and effectiveness concerns. |
| Note 2 | CASS is substantially equivalent to BSSFP and acquires two different phase cycling angle images and combine them by MIP operation to reduce dark band artifact.<br>The difference did not raise new safety and effectiveness concerns. |
| Note 3 | PASS is substantially equivalent to GRE and acquires two different type (SSFP_FID and SSFP_SE) echoes image and combine them to achieve hybrid contrast image. |
| Note 4 | In this submission, the noise control term was changed from total variation regularization to smoothed total variation regularization.<br>The difference did not raise new safety and effectiveness concerns. |
| Note 5 | EasyScan of the proposed device supports more body part than that of the predicate device. In this submission, shoulder and abdomen are included.<br>The difference did not raise new safety and effectiveness concerns. |
| Note 6 | QGuard-Imaging is expected for automatic monitoring of MR images for motion artifacts and providing real-time prompts to assist technicians in image quality control.<br>The difference did not raise new safety and effectiveness concerns. |
| Note 7 | EasyCrop is a function that enables automatic cropping of vascular images scanned with the TOF_3D protocol to simplify the workflow, which allows users to obtain interference-free vascular 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 TOF_3D will still be saved.<br>The difference did not raise new safety and effectiveness concerns. |
| Note 8 | MoCap-Monitoring is a motion monitoring module which is periodic and is inserted into a pulse sequence. It can realize real-time motion monitoring in imaging scanning and provides an alert when motion occurs.<br>The difference did not raise new safety and effectiveness concerns. |

## 8. Performance Data

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

### Non-Clinical Testing

Non-clinical testing including surface heating and image performance tests were conducted for the uPMR 790 to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device.

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

### Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI/AAMIES60601-1: 2005/ (R) 2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012) [IncludingAmendment2(2021)]Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-33 Ed. 4.0:2022 Medical Electrical Equipment - Part 2-33: Particular Requirements for The Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnostic
- IEC 60825-1: 2014, Edition 3.0, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-6:2010+A1:2013+A2:2020, Edition 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- IEC 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.
- NEMA MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- NEMA MS 2-2008(R2020), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images

- NEMA MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 4-2010, 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: 2016, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- NEMA NU 2-2018, Performance Measurements of Positron Emission Tomography

**Software**

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

**Biocompatibility**

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

**Other Standards and Guidance**

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

**Performance Verification**

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

- Performance evaluation report for ACS, DeepRecon, ImageGuard, MoCap-Monitoring, EasyCrop, EasyScan, Qscan, ASL 3D, Multiband, Silicon-Only Imaging, MARS+, 2D Flow, 4D Flow, Inline CEST, Inline Fact, T1rho, Inline T2 mapping, HYPER DPR, Digital Gating, HYPER Iterative and Inline T2 mapping.
- Performance evaluation report for Spectroscopy: Liver MRS, Breast MRS
- Sample clinical images for all clinical sequences and coils 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***

- DeepRecon

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

The training data of DeepRecon were collected from 264 volunteers. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulted in a total of 165,837 cases. 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.

DeepRecon has undergone performance testing and phantom test to verify its performance. The testing dataset for performance testing was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data for performance testing is entirely independent and does not share any overlap with the training data.

The test results demonstrate that DeepRecon on uPMR 790 performs equivalently to that on uMR Omega. The DeepRecon on uPMR 790 was shown to perform better than NADR (No DeepRecon) by measuring SNR and resolution. Meanwhile, results from the tests also demonstrated that DeepRecon maintained image qualities, such as

contrast and uniformity. The structure measurements on paired images verified that DeepRecon and NADR images of same structures were significantly the same.

- ACS

ACS is an acceleration reconstruction technique. By adding one more regularization term from AI module, ACS is a slight extension of CS (Compressed Sensing).

The training dataset of AI module in ACS was collected from a variety of anatomies, image contrasts, and acceleration factors. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulting in a large number of cases. Fully-sampled k-space data were collected and transformed to image space as the ground-truth. The input data were generated by sub-sampling the fully-sampled k-space data with different parallel imaging acceleration factors and partial Fourier factors. All data were manually quality controlled before included for training.

The training and test datasets are collected from 35 volunteers, including 24 males and 11 females, ages ranging from 18 to 60. The samples from these volunteers are distributed randomly into training and test datasets. The validation dataset is collected from 15 volunteers, including 10 males and 5 females, whose ages range from 18 to 60.

ACS has undergone the same tests as the predicate device uMR Omega to verify its performance. The testing dataset for performance testing was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data for performance testing is entirely independent and does not share any overlap with the training data. In addition, comparison tests were conducted between ACS on uPMR 790 and uMR Omega.

The ACS on uPMR 790 was shown to perform better than CS by measuring SNR and resolution. 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. The test results demonstrate that ACS on uPMR 790 performs equivalently to that on uMR Omega via K220332. The structure measurements on paired images verified that ACS and fully sampled images of same structures were significantly the same.

**Summary**

The features described in this premarket submission are supported with the results of the testing mentioned above, the uPMR 790 was found to have a safety and effectiveness profile that is similar to the predicate device.

## 9. Conclusion

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