November 14, 2022

Shanghai United Imaging Healthcare Co., Ltd.
℅ Xin Gao
Regulatory Affairs Specialist
NO. 2258 Chengbei Road, Jiading District
Shanghai, Shanghai 201807
CHINA

Re: K222540
Trade/Device Name: uPMR 790
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: OUO
Dated: October 21, 2022
Received: October 21, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
Magnetic Resonance and Nuclear Medicine Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222540

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.

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510 (k) SUMMARY

1. Date of Prepared

October 21, 2022

K222540

2. Sponsor Identification

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3. Identification of Proposed Device(s)

Trade Name: uPMR 790
Common Name: Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Model: uPMR 790
Product Code: OUO
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Device Class: II

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K192672
Device Name: uPMR 790
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO

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 Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance.
The modifications performed on the uPMR 790 (K192672) in this submission are due to the following changes that include:
(1) Addition and modification of pulse sequences:
   a) New sequences: hise, asl_3d, gre_quick_4dcemra, gre_maps.
   b) Added Associated options for certain sequences: navigator, T2* mapping, cardiac tagging, Perfusion, PSIR, Cine, cardiac T1 mapping, cardiac T2 mapping, cardiac T2* mapping, dark blood, SWI+ (multi-echo), cDWI, MicroView.
(2) Addition of MR imaging processing methods: Phase Sensitive Inversion Recovery (PSIR), Computed DWI (cDWI), Inline T1/T2* Map, Susceptibility Weighted Imaging Plus (SWI+), Arterial Spin Labeling (ASL), Cardiac T1 Mapping, Cardiac T2 Mapping, Cardiac T2* Mapping.
(3) Addition and modification of PET imaging processing methods:
   a) The new PET imaging processing method: Hyper Iterative.
   b) Modified MRAC method:WFI based head MRAC.
(4) Addition VSM models: uVWMERP and uMVRX.
(5) Addition Spectroscopy: HISE for Head Spectroscopy; Prostate Spectroscopy.

The modifications, which do not affect the intended use or alter the fundamental scientific technology of the device.

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. Technological Characteristic

The differences from the predicate device are discussed in the comparison table in this submission as below.

Table 1 Comparison of Hardware configuration

ITEM	This Submission uPMR 790	Predicate Device uPMR 790(K192672)	Remark
510(K) No.		K192672	
Product Code	OUO	OUO	Same
Regulation No.	21 CFR 892.1200	21 CFR 892.1200	Same
Class	II	II	Same
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	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	Same

	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.	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.	
Field Strength	3.0 Tesla	3.0 Tesla	Same
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	60cm	60cm	Same
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	2.400ppm @ 50cm DSV 0.800ppm @ 45cm DSV 0.390ppm @ 40cm DSV 0.110ppm @ 30cm DSV 0.038ppm @ 20cm DSV 0.020ppm @ 10cm DSV	2.400ppm @ 50cm DSV 0.800ppm @ 45cm DSV 0.390ppm @ 40cm DSV 0.110ppm @ 30cm DSV 0.038ppm @ 20cm DSV 0.020ppm @ 10cm DSV	Same
Max gradient amplitude	45mT/m	45mT/m	Same
Max slew rate	200T/m/s	200T/m/s	Same
Shielding	active	active	Same
Cooling	water	water	Same
Resonant frequencies	128.23MHz	128.23MHz	Same
Number of transmit channels	2	2	Same

Number of receive channels	48	48	Same
Amplifier peak power per channel	18kW	18kW	Same
Dimensions	width 640mm, height 890mm, length 2620mm	width 640mm, height 890mm, length 2620mm	Same
Maximum supported patient weight	250kg	250kg	Same
Vital Signal Gating	Wireless UIH Gating Unit REF 453564324621 ECG module Ref 989803163121 SpO2 module Ref 989803163111	Wireless UIH Gating Unit REF 453564324621 ECG module Ref 989803163121 SpO2 module Ref 989803163111 (alternative) uVWMERP uMVRX (alternative)	Note 1
PET			
Resolution	1cm:FWMH≤3.2mm 10cm:FWHM≤3.6mm 20cm:FWHM≤4.8mm	1cm:FWMH≤3.2mm 10cm:FWHM≤3.6mm 20cm:FWHM≤4.8mm	Same
Sensitivity	0cm: ≥14cps/kBq 10cm: ≥14cps/kBq	0cm: ≥15cps/kBq 10cm: ≥15cps/kBq	Note 2
Scatter fraction, count losses and randoms measurement	NECR peak:≥110kcps True peak: ≥300kcps Scatter Fraction: ≤0.46	NECR peak:≥110kcps True peak: ≥360kcps Scatter Fraction: ≤0.46	Note 3
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:≤12%	Note 4
Image quality	Contrast Recovery coefficient: 10mm: ≥45.0% 13mm: ≥55.0% 17mm: ≥55.0% 22mm: ≥65.0% 28mm: ≥65.0% 37mm: ≥70.0% Noise: 10mm: ≤9.0% 13mm: ≤8.0%	Contrast Recovery coefficient: 10mm: ≥45.0% 13mm: ≥55.0% 17mm: ≥55.0% 22mm: ≥65.0% 28mm: ≥65.0% 37mm: ≥70.0% Noise: 10mm: ≤9.0% 13mm: ≤8.0%	Note 5

	17mm: ≤7.0% 22mm: ≤7.0% 28mm: ≤7.0% 37mm: ≤7.0% Relative lung error:≤10%	17mm: ≤7.0% 22mm: ≤7.0% 28mm: ≤7.0% 37mm: ≤7.0% Relative lung error:≤16%	
Time of Fly(TOF) resolution	≤560ps	N.A.	Note 6
Safety			
Electrical Safety	IEC 60601-1	IEC 60601-1	Same
EMC	IEC60601-1-2	IEC60601-1-2	Same
Max SAR for Transmit Coil	IEC 60601-2-33	IEC 60601-2-33	Same
Max dB/dt	IEC 60601-2-33	IEC 60601-2-33	Same
Biocompatibility	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Same
Surface Heating	NEMA MS 14	ES 60601-1	Note 7

Note 1	Compared to the predicate device, the proposed device add an alternative VSM model (include uVWMERP and uMVRX). The trigger method, principle, connection mode, installation position and other aspects of this model are completely consistent with the original model.
Note 2	Comparing to the previous submission, the calibration factor of well-counter has been updated according to well-counter vendor's notice. The measured activity will be different based on the new factor. So the sensitivity specification, which depends on activity, shall be updated accordingly.
Note 3	The true peak value is updated to a wider criterion. It will not affected the system effectiveness, operator can achieve the equivalent counts by adjusting acquisition time.
Note 4	The accuracy specification update to a better criterion due to physical correction optimization. The superior specification will not affect the effectiveness and safety.
Note 5	The relative lung error specification update to a better criterion due to verification, it is reasonable to claim a better criterion. The superior specification will not affect the effectiveness and safety.
Note 6	The Time of Fly resolution is added according to the NEMA NU2-2018 standard. Time of Fly resolution improve the image signal noise ratio, it will not affect the effectiveness and safety.
Note 7	The NEMA standards publication MS 14-2019 describes the procedure for heating RF coil heating under worst-case normal operating conditions. The results for the surface heating test showed that proposed devices perform as well as or better than predicate devices.

Table 2 provides the new application software features of the proposed device in comparison to the predicate device.

Table 2 Comparison of the new Application Software Features

ITEM	This Submission uPMR 790	Predicate Device uPMR 790(K192672)	Remark
MR Image Processing Features			
Phase Sensitive Inversion Recovery (PSIR)	Yes	No	PSIR is substantially equivalent to FFT reconstruction and acquire real image from two TI (time-inversion) images which is benefit for more stable contrast.
Computed DWI (cDWI)	Yes	No	cDWI is substantially equivalent to DWI and generates fitting b-value from multiple acquisition b values.
Inline T1/T2* Map	Yes	No	Inline T1/T2* Map is substantially equivalent to T1/T2* Map processed by post-processing module. The map result displays inline without extra operation by post-processing module.
Susceptibility Weighted Imaging Plus (SWI+)	Yes	No	SWI+ is substantially equivalent to SWI and acquires multi-echo to achieve more information than SWI.
Arterial Spin Labeling (ASL)	Yes	No	ASL is substantially equivalent to FSE and uses extra arterial spin labeling preparation and imaging processing for cerebral blood flow (CBF) imaging without contrast agent.
Cardiac T1 Mapping	Yes	No	Cardiac T1 mapping is substantially equivalent to GRE and uses multiple TI acquisitions with IR preparation and imaging processing for cardiac T1 mapping.
Cardiac T2 Mapping	Yes	No	Cardiac T2 mapping is substantially equivalent to

			GRE and uses multiple T2-prep duration preparation acquisitions and imaging processing for cardiac T2 mapping.
Cardiac T2* Mapping	Yes	No	Cardiac T2* mapping is substantially equivalent to GRE and uses multiple TE acquisitions and imaging processing for cardiac T2* mapping.
PET Image Processing Features			
Hyper Iterative	Yes	No	HYPER Iterative is a regularized iterative reconstruction algorithm which incorporates a noise control term into the iterative process. It allows more iterations while remains the image noise at an acceptable level. HYPER Iterative can achieve high image contrast and quantification accuracy compared with OSEM algorithm.
WFI based head MRAC	Yes	No	Note 8
Spectroscopy Features			
HISE of Head Spectroscopy	Yes	No	HISE technique is added in Head spectroscopy and has no change of spectroscopy principle. It is short for High SNR and high bandwidth and have better performance than general technique.
Prostate Spectroscopy	Yes	No	Prostate spectroscopy is substantially equivalent to spectroscopy and uses characteristic metabolites detection post processing for prostate spectroscopy.
Workflow Features			
Easy Scan	Yes	No	Easy Scan feature allows automatic slice positioning for cardiac, c-spine and knee imaging. The positioning can

			also be adjusted manually by user. The final positioning effect is equivalent to manual operation without Easy Scan feature.
Easy Plan	Yes	No	With the built-in planning rules, Easy Plan feature allows automatic whole-body bed position planning for different size of patient. The final positioning effect is equivalent to manual operation without Easy Plan feature.

Note 8	The new Water Fat Imaging (WFI) based PET head attenuation correction is an improvement over the previous UTE (Ultra short Time-to-Echo) based method. The new method is based on DIXON Water and Fat Imaging (WFI technique and Quick3d (Also termed fast low angle shot, FLASH) MR sequence. In this method, an AI module, which essentially is a Convolution Neural Network (CNN) was used to generate three masks of air, cortical bone and a mixed compartment containing soft tissue and fat, then the mixed compartment was separated into soft tissue and fat using an image intensity threshold. The network training process uses pairs of WFI images and three-compartment segmentation from CT images of the same person. Information about training and validation dataset is shown below. Training dataset: Gender, 76 male 54 female, Age 17-83; Ethnicity, Chinese; Test set: Gender, 17 male, 10 female; Age: 15-78; Ethnicity: Chinese Test data from Center 2 (n=12) was initially excluded from the training set and were from completely different subjects. All the data from Center1 (n=10) was collected almost 2 years after the imaging date of the training data, also with different subjects compared with the training set. Therefore, the test data was completely independent from the training data. The acceptance criteria is that average SUVmean error (CTAC as reference) in major brain regions cross the test patient cohort is within 10%, which is consistent with previous literatures using similar evaluation methodology. The test results fulfills this criteria, with most brain regions having average error below 3%.

8. Performance Data

The following testing was performed as described in the guidance /standards:

- ES 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2 Medical electrical equipment Part 1-2: General Requirements for basic safety and essential Performance
- IEC 60601-2-33 Ed. 3.1:2013, Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 6-2008(R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems
- NEMA NU 2 Performance Measurements of Positron Emission Tomography

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

- Clinical performance evaluation
- Performance evaluation report for 3D ASL (asl3d sequence), Inline Mapping，Cardiac T1 Mapping, Cardiac T2 Mapping, Cardiac T2* Mapping, Hyper Iterative, MRAC with AI-HITS, brain Spectroscopy, prostate Spectroscopy, EasyScan, EasyPlan.
- PET/MR image quality test report

The test results demonstrated that the device performs as expected and thus, it is substantially equivalent to the predicate devices to which it has been compared.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, we concludes that uPMR 790 Magnetic Resonance Diagnostic Device is substantially equivalent to the predicate device. It does not introduce new indications for use, and has the same technological characteristics and does not introduce new potential hazards or safety risks.