



Shanghai United Imaging Healthcare Co., Ltd.
% Shumei Wang
QM & RA VP
No. 2258 Chengbei Rd., Jiading Industrial District
Shanghai, Shanghai 201807
CHINA

February 27, 2019

Re: K183014
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: January 22, 2019
Received: January 23, 2019

Dear Shumei Wang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K183014

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-centrally. 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

K183014

1. Date Prepared [21 CFR 807.92(a)(1)]

October 29, 2018

2. General Information [21 CFR 807.92(a)(1)]

Manufacturer: Shanghai United Imaging Healthcare Co., Ltd
2258 Chengbei Rd., Jiading District, Shanghai, 201807

Contact Person: Shumei WANG
QM&RA VP
Tel: +86 (21) 67076888-6776
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Email: shumei.wang@united-imaging.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

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

4. Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]

The identification of predicates device within this submission is as follow:

Predicate Device

Manufacturer: GE Healthcare
Device Name: SIGNA PET/MR
Product Code: OUO
Device Class: II
Regulation Number: 21 CFR 892.1200
FDA 510 (k) #: K142098

5. Device Description [21 CFR 807.92(a)(4)]

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.

6. Intended Use [21 CFR 807.92(a)(5)]

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-centrally. 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 [21 CFR 807.92(a)(6)]

The uPMR 790 has the similar major technological characteristics as the predicate device. The differences from the predicate device including high order shimming configuration, interventional usage, RFPA power, geometrical dimensions of PET detector, and external triggering function are discussed in the comparison table in this submission. The same scientific technology theory, similar physical design, same coil applications and functionalities are applied to both the uPMR 790 and predicate device. The technical characteristic differences do not affect the safety and effectiveness of the uPMR 790 for intended use.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Summary of Non-Clinical Tests:

The following testing was conducted on the uPMR 790 system:

- ES60601-1:2005/(R)2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 4.0 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- 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
- IEC 60825-1 Edition 2.0 2007-03, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
- 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(R2014), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 2-2008(R2014), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- MS 3-2008(R2014), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- MS 5-2010, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- MS 6-2008(R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- MS 8-2008, Characterization Of The Specific Absorption Rate For Magnetic Resonance Imaging Systems
- MS 9-2008(R2014), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA NU 2-2012 Performance Measurements of Positron Emission Tomography

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.

Summary of Clinical Tests:

Sample clinical images were provided to support the ability of uPMR 790 to generate diagnostic quality images.

9. Conclusion [21 CFR 807.92(b)(3)]

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.