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

November 20, 2019

Re: K192672
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: September 25, 2019
Received: September 26, 2019

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192672

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 K192672

1. Date of Prepared

September 25, 2019

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
Device Class: II

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K183014
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 (K183014) in this submission are due to the change of the magnet, volume transmit coil, receive coils and PET gantry.

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

- Introduce a new magnet
- Change the PET gantry structure and RF shield
- Introduce six new receive coils and new categorization of coils

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

A new magnet model is introduced in uPMR 790 and critical specifications of the main magnet are as same as the predicate device including field strength, magnet

dimension and field homogeneity. The mechanical structure of PET gantry and RF shield are modified to provide better system integration and both PET and RF characteristics are tested and validated to show substantially equivalence to those of the predicate device.

Six new receive coils are added including: Head Coil - 32, Foot & Ankle Coil -24, Cardiac Coil- 24, Temporomandibular Joint Coil - 4, Carotid Coil - 8, Infant Coil - 24. Also seven receive coils are categorized as PET/MR coils with gamma ray attenuation and scattering data characterized in uPMR 790.

Overall the technology characteristics of the uPMR 790 with modified hardware and new coils, reflected in this 510(k) submission, are fundamentally equivalent to those of the predicate device.

8. Performance Data

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

Non-Clinical Testing

The following testing was conducted on the proposed devices:

- ES60601-1, 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 - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- IEC 60601-2-33, Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic
- NEMA NU 2 Performance Measurements of Positron Emission Tomography
- Signal to Noise Ratio
- Geometric Distortion
- Image Uniformity
- Magnetic Field Homogeneity
- Magnetic Field Decay
- PET/MR Attenuation Correction
- Acoustic Noise
- Surface Heating of RF Receive Coils

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.

Clinical Testing

No clinical testing was conducted on the proposed devices.

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.