December 18, 2018

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

Re: K182938
Trade/Device Name: uEXPLORER
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: October 17, 2018
Received: October 23, 2018

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,

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182938

Device Name
uEXPLORER

Indications for Use *(Describe)*
The uEXPLORER PET/CT is a diagnostic imaging system that combines two existing imaging modalities - PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing the metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.

This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and treatment response evaluation for diseases and disorders in, but not limit to, oncology, cardiology and neurology.

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.

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"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."

510(k) SUMMARY

1. **Date of Preparation:** October 17, 2018

2. **Sponsor Identification**

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

Contact Person: Shumei Wang
Position: QM&RA VP
Tel: +86-021-67076888-6776
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3. **Identification of Proposed Device**

Trade Name: uEXPLORER
Common Name: Emission Computed Tomography System

Model(s): uEXPLORER

Regulatory Information
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK,
Review Panel: Radiology

4. **Identification of Predicate Device(s)**

510(k) Number: K172143
Device Name: uMI 780
Model(s): uMI 780

Regulatory Information
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK,
Review Panel: Radiology

5. Device Description

The uEXPLORER PET/CT system is a combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanner. This system is intended to be operated by qualified healthcare professionals for performing diagnostic imaging examinations. The spatial alignment and precise image registration between PET and CT ensure the PET and CT images of the same region can be fused accurately for reading. PET measures the distribution of PET radiopharmaceuticals inside the human body quantitatively. CT produces the anatomical information of the same scanned region, and provides accurate localization for the findings in the PET images. The attenuation information contained in the CT images can be utilized in the PET image reconstruction to ensure quantitation accuracy. The PET system has time-of-flight capability with a timing resolution of 430ps. It has a 1940mm-long axial field of view (FOV) and the system sensitivity is 191 cps/kBq.

The uEXPLORER PET/CT system also includes a patient table, a workstation with associated software installed. The software is used for patient management, data management, scan control, image reconstruction and image reading. All patient images produced by the system conform to the DICOM 3.0 standard.

6. Indications for Use

The uEXPLORER PET/CT is a diagnostic imaging system that combines two existing imaging modalities - PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing the metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.

This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and

treatment response evaluation for diseases and disorders in, but not limit to, oncology, cardiology and neurology.

7. Comparison of Technological Characteristics with the Predicate Devices

The uEXPLORER PET/CT has the same indications for use as the predicate device uMI 780 PET/CT. The fundamental scientific technology of the proposed device is same as the predicate device.

Table 1 below provides a comparison of the technological characteristics of the proposed device in comparison to the predicate device.

Table 1 Comparison of Technological Characteristics

ITEM	**Proposed Device**	**Predicate Device**
Product Code	KPS, JAK	KPS, JAK
Regulation No.	21 CFR 892.1200	21 CFR 892.1200
Class	Class Ⅱ	Class Ⅱ
Intended Use	The uEXPLORER PET/CT is a diagnostic imaging system that combines two existing imaging modalities - PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing the metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.	The uMI 780 PET/CT is a diagnostic imaging system that combines two existing imaging modalities - PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing the metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.

	This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and treatment response evaluation for diseases and disorders in, but not limit to, oncology, cardiology and neurology.	This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and treatment response evaluation for diseases and disorders in, but not limit to, oncology, cardiology and neurology.
PET Specification		
Sensitivity	＞/=170cps/kBq	＞/=15cps/kBq
NECR Peak Value	＞/=1400 kcps@16kBq/cc	＞/=165kcps@16kBq/cc
Peak True Count Rate	＞/=4500kcps@28kBq/cc	＞/=500kcps@30kBq/cc
PET Scatter Fraction	＜/＝0.44	＜/＝0.44
Count Rate Bias	＜/＝±5%	＜/＝±5%
Axial FWHM@1cm	＜/=3.5mm	＜/=3.5mm
Transaxail FWHM@1cm	＜/=3.5mm	＜/=3.5mm
Axial FWHM@10cm	＜/=4.0mm	＜/=4.0mm
Transaxial FWHM@10cm	＜/=4.0mm	＜/=4.0mm
CT Specification		
Scan Regime	Continuous Rotation	Continuous Rotation
Scan Modes	Topo Axial Scan Helical Scan	Topo Axial Scan Helical Scan
Z-plane coverage	40mm	40mm
Number of detector row	80	80
Minimum slice thickness	0.5mm	0.5mm
Rotation speed	Up to 0.3 sec for 360° rotation	Up to 0.3 sec for 360° rotation
Table Maximum table load	250kg	250kg

Safety		
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
EMC	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 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
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).

8. Performance Data

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

Non-Clinical Testing

Non-clinical testing including dosimetry and system performance tests were conducted for the uEXPLORER during the product development.

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

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the uEXPLORER in accordance with the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard:

Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-44 Edition 3.2: 2016 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
- IEC 60601-1-3 Edition 2.1 2013-04 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- 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)]

Product Particular Standards
- IEC 61223-3-5 First edition 2004-08 Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests -Imaging performance of computed tomography X-ray equipment [Including: Technical Corrigendum 1 (2006)]
- NEMA XR 25-2010: Computed Tomography Dose Check
- NEMA XR 28-2013 Supplemental Requirements for User Information and System Function Related to Dose in CT
- NEMA XR 29-2013: Standard Attributes on CT Equipment Related to Dose Optimization and Management

Performance Verification
- NEMA NU 2-2012 Performance Measurements of Positron Emission Tomographs;
- Extended Performance Test Report for performance study;
- Clinical Evaluation for sample clinical images evaluation;
- AEC Test Report for AEC performance study.

Software
- NEMA PS 3.1-3.20(2011): Digital Imaging and Communications in Medicine (DICOM)
- IEC 62304: Medical Device Software - software life cycle process
- 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 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Other Standards and Guidances
- ISO 14971: 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
- Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; Guidance for Industry and FDA Staff (Laser Notice No. 50)
- Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography

Software Verification and Validation
Software documentation for a Moderate Level of Concern software per FDA' Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is included as a part of this submission.

The risk analysis was completed and risk control was implemented to mitigate identified hazards. The testing results show that all the software specifications have met the acceptance criteria. Verification and validation testing of the proposed device was found acceptable to support the claim of substantial equivalence.

UNITED IMAGING HEALTHCARE conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modification, misuse or denial of use, or unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" is included in this submission.

Clinical Testing
No Clinical Study is included in this submission.

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

9. Conclusions

Based on the comparison and analysis above, the proposed device has same intended use, similar performance, equivalence safety and effeteness 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.