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

April 13, 2018

Re: K172143
Trade/Device Name: uMI 780 PET/CT System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK,
Dated: March 10, 2018
Received: March 13, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara For

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

Enclosure

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UNITED IMAGING

Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drup Administration
Indications for Use

Form Approved:OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number(if known)

K172143

Device Name

uMI 780 PET/CT System

Indications for Use (Describe):

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.

Type of use:

☒Precription Use (Part 21 CFR 801 Subpart D) ☐Over-The-Counter Use (Part 21 CFR 801 Subpart D)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 16

510(k) Summary

510(k) SUMMARY

1. Date of Preparation: March 9, 2018

2. Sponsor Identification

Client Name：	Shanghai United Imaging Healthcare Co.,Ltd.
Client Address:	NO.2258 Chengbei Road, Jiading District, Shanghai,China
Establishment Registration Number:	Not yet registered
Contact Person:	Wang Shumei
Position:	QM&RA VP
Tel:	+86-21-67076888-6776
Fax:	+86-21-67076889
Email:	shumei.wang@united-imaging.com

3. Identification of Proposed Device

Model(s):	uMI 780
Trade Name:	uMI 780
Common Name:	Positron Emission Tomography and Computed Tomography System
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200 Computed Tomography X-Ray System per 21 CFR 892.1750
Regulation Number:	21 CFR 892.1200
Product Code:	KPS and JAK
Review Panel:	Radiology
Classification:	Class II

4. Proposed Device Description

The uMI 780 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 520ps. It has a 300mm-long axial field of view (FoV) and a system sensitivity higher than 15cps/kBq.

The uMI 780 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.

5. Intended Use Statement of Proposed Device

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.

6. Identification of Predicate Device(s)

510(k) Number:	K151486
Product Name:	Positron Emission Tomography (PET) System Computed Tomography (CT) System
Model Name:	Biograph mCT and mCT Flow PET/CT Scanners

7. Non-clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- Recognition Number 19-4:AAMI ANSI ES60601-1: 2005/(R)2012 and A1:2012
- Recognition Number 12-269:IEC 60601-1-3: Edition 2.1
- Recognition Number 12-257:IEC 60601-2-44: Edition 3.0
- Recognition Number 19-1:IEC 60601-1-2: Edition 3
- Recognition Number 12-273:IEC 60825-1:Edition 2.0
- Recognition Number 12-270:NEMA 61223-3-5: First edition
- Recognition Number 12-265:NEMA NU 2:2012
- Recognition Number 2-174:ISO 10993-10:Third Edition
- Recognition Number 2-245:ISO 10993-5:Third edition
- Recognition Number 12-225:NEMA XR 25: 2010
- Recognition Number 12-287:NEMA XR 28:2013
- NEMA XR 29:2013

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantial Equivalence Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	KPS,JAK	KPS,JAK
Regulation No.	21 CFR 892.1200	21 CFR 892.1200
Class	II	II
Intended Use	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.	The Siemens Biograph mCT systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information. The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images. The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging. These systems are intended to be utilized by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

Item	Proposed Device(s)	Predicate Device(s)
PET Specification		
Sensitivity	＞/=15cps/kBq	＞/=9.4cps/kBq
NECR Peak Value	＞/=165kcps@16kBq/cc	＞/=165 kcps@28kBq/cc
Peak True Count Rate	＞/=500kcps@30kBq/cc	＞/=575kcps@40kBq/cc
PET Scatter Fraction	＜/＝0.44	＜/＝40%
Count Rate Bias	＜/＝±5%	＜/＝±5%
Axial FWHM@1cm	＜/=3.5mm	＜/=6.0mm
Transaxail FWHM@1cm	＜/=3.5mm	＜/=7.3mm
Axial FWHM@10cm	＜/=4.0mm	＜/=6.6mm
Transaxial FWHM@10cm	＜/=4.0mm	＜/=7.5mm
CT Specification		
Scan Regime	Continuous Rotation	Continuous Rotation
Scan Modes	Topo Axial Scan Helical Scan	Topo Axial Scan Helical Scan
Z-plane coverage	40mm	38.4mm
Number of detector row	80	64
Minimum slice thickness	0.5mm	0.6mm
Rotation speed	Up to 0.3 sec for 360 °rotation	Up to 0.3 sec for 360 °rotation
Table Maximum table load	250kg	227kg
Safety		
Biocompatibility	Comply with ISO 10993-5,ISO 10993-10	Comply with ISO 10993-5,ISO 10993-10
Electrical Safety	Comply with ES 60601-1	Comply with ES 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

Testing in accordance with the FDA standards for ionizing radiation emitting products and equipment with laser lights were passed and the test results were documented.

Performance testing in accordance with NEMA NU2:2012 was conducted and met the predetermined acceptance values. The test results were documented.

The device’s labeling contains the operator’s manuals for the system and software operations, the technical instructions, and necessary labels for safe and effective use of the device.

10. Substantially Equivalent (SE) Conclusion

The uMI 780 PET/CT system is intended for the same use as and functions in a similar manner to the predicate device. With the proof of conformance to applicable standards, successful completion of software validation and performance test results presented in this submission, it is concluded that the uMI 780 PET/CT system is as safe, effective and is substantially equivalent to the predicate device.