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

January 26, 2020

Re: K193241
Trade/Device Name: uMI 550
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: November 22, 2019
Received: November 25, 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/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)*
K193241

Device Name
uMI 550

Indications for Use *(Describe)*
The uMI 550 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.

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510(k) SUMMARY

1. **Date of Preparation:** January 22, 2020

2. **Sponsor Identification**

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

Contact Person: Shumei Wang
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Email: shumei.wang@united-imaging.com

3. **Identification of Proposed Device**

Trade Name: uMI 550
Common Name: Emission Computed Tomography System

Model(s): uMI 550

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)**

Predicate Device

510(k) Number: K182237
Device Name: uMI 550
Model(s): uMI 550

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 uMI 550 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 uMI 550 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.

The uMI 550 PET/CT has been previously cleared by FDA via K182237. The modifications performed on the uMI 550 PET/CT (K182237) in this submission are due to the addition of HYPER Iterative and Auto-Planbox function. Meanwhile the sensitivity specification has been updated. HYPER Iterative allows more iterations while remains the image noise at an acceptable level by incorporating a noise control term into the objective function. HYPER Iterative can achieve high image contrast and quantification accuracy. Auto-Planbox plan the scan range by recognizing body parts on CT scout image. It locates the different body parts based on anatomy characteristic. The scan range is generated to cover the whole body parts according to protocol selection. This function will simplify scanning process, which will be convenient for user operation.
The modifications are listed as follow:

- Introduce HYPER Iterative function.
- Introduce Auto-Planbox function.
- Update sensitivity specification.

	uMI 550 PET/CT previous submission(K182237)	uMI 550 PET/CT this submission	Remark
Sensitivity	＞/=10cps/kBq @0cm ＞/=10cps/kBq @10cm	＞/=9cps/kBq @0cm ＞/=9cps/kBq @10cm	Sensitivity specification has been updated.
HYPER Iterative	Not available	Available	New function has been added
Auto-Planbox	Not available	Available	New function has been added

6. Indications for Use

The uMI 550 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 technology characteristics of the modified uMI 550, reflected in this 510(k) submission, do not alter the scientific technology of the devices and are substantially equivalent to those of the predicate devices.

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 uMI 550	Predicated Device uMI 550(K182237)	Remark
General			
Product Code	KPS, JAK	KPS, JAK	Same
Regulation No.	21 CFR 892.1200	21 CFR 892.1200	Same
Class	Class Ⅱ	Class Ⅱ	Same
Intended Use	The uMI 550 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 uMI 550 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.	Same

Specifications				
PET Specifications				
Scintillator material		LYSO	LYSO	Same
Scintillator dimensions		2.76mm×2.76mm×16.3 mm	2.76mm×2.76mm×16.3 mm	Same
Number of detector rings		84	84	Same
Number of image planes		167	167	Same
Axial field of view		24cm	24cm	Same
Image matrix sizes		128×128, 150×150, 192×192，256×256, 512×512, 600×600	128×128, 150×150, 192×192，256×256, 512×512, 600×600	Same
Coincidence window		4.0ns	4.0ns	Same
Spatial Resolution	Axial FWHM@1cm	＜/=3.5mm	＜/=3.5mm	Same
	Transaxial FWHM@1cm	＜/=3.5mm	＜/=3.5mm	
	Axial FWHM@10cm	＜/=4.0mm	＜/=4.0mm	
	Transaxial FWHM@10cm	＜/=4.0mm	＜/=4.0mm	
Sensitivity		＞/=9cps/kBq	＞/=10cps/kBq	Note No.1
NECR Peak Value		＞/=90 kcps@13kBq/cc	＞/=90 kcps@13kBq/cc	Same
Peak True Count Rate		＞/=300kcps@27kBq/cc	＞/=300kcps@27kBq/cc	Same
PET Scatter Fraction		＜/＝0.44	＜/＝0.44	Same
Count Rate Bias		＜/＝±5%	＜/＝±5%	Same
Image Quality		Acceptance Value	Acceptance Value	Same
		Sphere / Contrast Recovery / Background variability	Sphere / Contrast Recovery / Background variability	
		10 mm / ⩾45.0% / <7.5%	10 mm / ⩾ 45.0% / <7.5%	
		13 mm / ⩾55.0% / <7.0%	13 mm / ⩾ 55.0% / <7.0%	
		17 mm / ⩾65.0% / <7.0%	17 mm / ⩾ 65.0% / <7.0%	

	22 mm	≥72.0%	<7.0%	22 mm	≥ 72.0%	<7.0%	
	28 mm	≥65.0%	<7.0%	28 mm	≥ 65.0%	<7.0%	
	37 mm	≥70.0%	<7.0%	37 mm	≥ 70.0%	<7.0%	
	Lung Residual	≤16.0%	<7.0%	Lung Residual	≤ 16.0%	<7.0%	
CT Specifications							
Scan Regime	Continuous Rotation			Continuous Rotation			Same
Scan Modes	Topo Axial Scan Helical Scan			Topo Axial Scan Helical Scan			Same
Detector Material	Solid-state GOS			Solid-state GOS			Same
Z-plane coverage	22mm			22mm			Same
Size of detector element in Z-plane	0.55mm			0.55mm			Same
Number of element per row	864			864			Same
Number of detector row	40			40			Same
Maximum slices generated per rotation (multi-slice capability)	80			80			Same
Minimum slice thickness	0.55mm			0.55mm			Same
Maximum sampling rate	Up to 4800 views per 360°			Up to 4800 views per 360°			Same
Tube anode storage capacity	5.3MHU			5.3MHU			Same
Maximum cooling rate	815 kHU/min			815 kHU/min			Same
Focal spot size	0.5x1.0mm 1.0x1.0mm			0.5x1.0mm 1.0x1.0mm			Same
Power	50 kW			50 kW			Same
mA Range	10-420mA			10-420mA			Same
kV Settings	70, 80, 100, 120, 140			70, 80, 100, 120, 140			Same
Aperture	700mm			700mm			Same
Rotation speed	Up to 0.5 sec per 360° rotation			Up to 0.5 sec per 360° rotation			Same
Image Spatial Resolution	High mode: ＞20 lp/cm @ MTF 0%			High mode: ＞20 lp/cm @ MTF 0%			Same

	16.5±1.7 lp/cm @ MTF10% 11.5±1.2 lp/cm @ MTF50%	16.5±1.7 lp/cm @ MTF10% 11.5±1.2 lp/cm @ MTF50%	
Image Noise	3.0±0.5 HU at 120 kV, 5 mm slice thickness, CTDIvol 28.9 mGy	3.0±0.5 HU at 120 kV, 5 mm slice thickness, CTDIvol 28.9 mGy	Same
CT Number Display Range	-1024 ~+8191 HU	-1024 ~+8191 HU	Same
Scan Field of View	Up to 500 mm	Up to 500 mm	Same
Reconstruction Field of View	40mm-500mm 40mm-600mm with extend FOV	40mm-500mm 40mm-600mm with extend FOV	Same
Image Matrix	Up to 1024 x 1024	Up to 1024 x 1024	Same
Reconstructed slice thickness	0.55mm,1.1mm,2.2mm, 5.5mm,11mm (axial) 0.55-10mm(helical)	0.55mm,1.1mm,2.2mm, 5.5mm,11mm (axial) 0.55-10mm(helical)	Same
Pitch	0.1~2.0	0.1~2.0	Same
Maximum continuous exposure time	Up to 100seconds	Up to 100seconds	Same
Others Specifications			
Display	24inch, 1920 x 1200	24inch, 1920 x 1200	Same
Horizontal motion range	2160 mm	2160 mm	Same
Vertical motion range	550 mm-945 mm from the floor	550 mm-945 mm from the floor	Same
Maximum horizontal scannable range	Standard 1700mm with up to full 2000mm.	Standard 1700mm with up to full 2000mm.	Same
Table Horizontal Speed	Up to 200mm/sec	Up to 200mm/sec	Same
Vertical speed	Up to 40 mm/sec	Up to 40 mm/sec	Same
Table Horizontal Position accuracy	±0.25mm	±0.25mm	Same
Table Maximum table load	250kg	250kg	Same
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	Same
EMC	IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential	IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential	Same

	performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	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).	Same
Clinical	Comparing with the predicate device, the difference of clinical image is due to the addition of HYPER Iterative function. The comparison sample images showed improved image contrast, resolution and increased SNR.		
Justification			
Note ID	Justification		
Note 1	Since activity measurement factor has been updated according to well-counter vendor's notice. The sensitivity specification, which depends on activity measurement, shall be updated accordingly. Provide the lower system sensitivity for PET imaging which would be compensated by a little longer scan time. The difference of the system sensitivity from the two devices does not affect the safety and effectiveness.		

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 image performance tests were conducted for the uMI 550 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 uMI 550 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 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 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 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
- Clinical Image Evaluation for sample clinical images
- AEC Test for AEC performance study
- Performance Evaluation for HYPER Iterative function
- Performance Evaluation for Auto-Planbox function

Bench testing was performed to support substantial equivalence and the product performance claims. For HYPER Iterative function, the evaluation and analysis used the identical raw datasets obtained on UIH's uMI 550 system and then applied both OSEM and HYPER Iterative. The resultant images were compared for:

- Quantification accuracy and signal to noise ratio (SNR) using the NEMA IQ phantom
- Lesion detectability using patient data
- Influence of regularization parameter selection using patient data
- Effectiveness for large weight patient
- Image contrast improvement on brain imaging

Bench testing showed that HYPER Iterative can be used in PET body and brain imaging, can provide the flexibility to achieve user-preferable image by adjusting the regularization parameter, and its images have demonstrated improved image quality, higher quantification accuracy, and improved image SNR than OSEM images.

For Auto-Planbox function, the evaluation and analysis used 16 group scout images and compared Auto-Planbox recognition with manual annotation body parts position. Bench testing results showed that Auto-Planbox can locate head center position, body

start position and body end position with proper accuracy and can assist operator to plan the scan range.

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 Image Evaluation

The reader study used a total of 20 retrospectively collected clinical cases. The raw data from each of these cases was reconstructed with both OSEM and HYPER Iterative. Each image was read by 3 American board-certified nuclear medicine

physicians who provided an assessment of image contrast according to 3-point scale ("+" represents better contrast image for small lesion detection; "-"represents worse contrast image for small lesion detection; "="represents similar contrast image for small lesion detection), and image quality according to a 5-point scale (1= images are unreadable and cannot be used for diagnosis, 2=insufficient image quality and may affect diagnosis; 3=image quality is barely ok for diagnosis; 4=image quality is sufficient for diagnosis; 5=wonderful image quality for diagnosis). The results of the study indicated that HYPER Iterative has better image contrast than OSEM and the image quality is sufficient for clinical diagnosis.

Clinical Testing
No Clinical Study is included in this submission.

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.