July 17, 2025

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

Re: K251839
Trade/Device Name: uMI Panvivo (uMI Panvivo); uMI Panvivo (uMI Panvivo S)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 13, 2025
Received: June 16, 2025

Dear Gao Xin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ningzhi Li -S Digitally signed by Ningzhi Li -S

for
Daniel M. Krainak, PhD
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251839

Please provide the device trade name(s).

uMI Panvivo (uMI Panvivo);
uMI Panvivo (uMI Panvivo S)

Please provide your Indications for Use below.

The uMI Panvivo is a PET/CT system designed for providing anatomical and functional images. The PET provides the distribution of specific radiopharmaceuticals. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. PET and CT scans can be performed separately. The system is intended for assessing metabolic (molecular) and physiologic functions in various parts of the body. When used with radiopharmaceuticals approved by the regulatory authority in the country of use, the uMI Panvivo system generates images depicting the distribution of these radiopharmaceuticals. The images produced by the uMI Panvivo are intended for analysis and interpretation by qualified medical professionals. They can serve as an aid in detection, localization, evaluation, diagnosis, staging, re-staging, monitoring, and/or follow-up of abnormalities, lesions, tumors, inflammation, infection, organ function, disorders, and/or diseases, in several clinical areas such as oncology, cardiology, neurology, infection and inflammation. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

The CT system can be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.*

* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Please select the types of uses (select one or both, as applicable).

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

510(k) SUMMARY

K251839

1. **Date of Preparation**
   July 16, 2025

2. **Sponsor Identification**

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

   Contact Person: Xin GAO
   Position: Regulatory Affair Manager
   Tel: +86-021-67076888-5386
   Fax: +86-021-67076889
   Email: xin.gao@united-imaging.com

3. **Identification of Proposed Device**

   Device Name: uMI Panvivo
   Common Name: Positron Emission Tomography and Computed Tomography System
   Model(s): uMI Panvivo， uMI Panvivo S

   Regulatory Information
   Regulation Number: 21 CFR 892.1200, 21 CFR 892.1750
   Regulation Name: Emission Computed Tomography System
   Regulatory Class: II
   Product Code: KPS, JAK
   Review Panel: Radiology

4. **Identification of Primary/Reference Device(s)**

   Predicate Device

   510(k) Number: K243538
   Device Name: uMI Panvivo
   Regulation Name: Emission Computed Tomography System
   Regulatory Class: II
   Product Code: KPS, JAK
   Review Panel: Radiology

   Reference Device#1
   510(k) Number: K232712
   Device Name: uMI Panorama
   Model(s): uMI Panorama 28, uMI Panorama 35

Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

Reference Device#2

510(k) Number: K193210
Device Name: HYPER DLR
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS
Review Panel: Radiology

5. Device Description:

The proposed device uMI Panvivo combines a 295/235 mm axial field of view (FOV) PET and 160-slice CT system to provide high quality functional and anatomical images, fast PET/CT imaging and better patient experience. The system includes PET system, CT system, patient table, power distribution unit, control and reconstruction system (host, monitor, and reconstruction computer, system software, reconstruction software), vital signal module and other accessories.

The uMI Panvivo has been previously cleared by FDA via K243538.The main modifications performed on the uMI Panvivo (K243538) in this submission are due to the addition of Deep MAC(also named AI MAC) , Digital Gating(also named Self-gating) , OncoFocus(also named uExcel Focus and RMC) , NeuroFocus(also named HMC) , DeepRecon.PET (also named as HYPER DLR or DLR), uExcel DPR (also named HYPER DPR or HYPER AiR)and uKinetics. Details about the modifications are listed as below:

- Deep MAC, Deep Learning-based Metal Artifact Correction (also named AI MAC) is an image reconstruction algorithm that combines physical beam hardening correction and deep learning technology. It is intended to correct the artifact caused by metal implants and external metal objects. .
- Digital Gating (also named Self-gating, cleared via K232712) can automatically extract a respiratory motion signal from the list-mode data during acquisition which called data-driven (DD) method. The respiratory motion signal was calculated by tracking the location of center-of-distribution(COD) in body cavity mask. By using the respiratory motion signal, system can perform gate reconstruction without respiratory capture device.
- OncoFocus (also named uExcel Focus and RMC, cleared via K232712) is an AI-based algorithm to reduce respiratory motion artifacts in PET/CT images and at the same time reduce the PET/CT misalignment.
- NeuroFocus (also named HMC) is head motion correction solution, which employs a statistics-based head motion correction method that correct motion

artifacts automatically using the centroid-of-distribution (COD) without manual parameter tuning to generate motion free images.

- DeepRecon.PET (also named as HYPER DLR or DLR, cleared via K193210) uses a deep learning technique to produce better SNR (signal-to-noise-ratio) image in post-processing procedure.
- uExcel DPR (also named HYPER DPR or HYPER AiR, cleared via K232712) is a deep learning-based PET reconstruction algorithm designed to enhance the SNR of reconstructed images. High-SNR images improve clinical diagnostic efficacy, particularly under low-count acquisition conditions (e.g., low-dose radiotracer administration or fast scanning protocols).
- uKinetics(cleared via K232712) is a kinetic modeling toolkit for indirect dynamic image parametric analysis and direct parametric analysis of multipass dynamic data. Image-derived input function (IDIF) can be extracted from anatomical CT images and dynamic PET images. Both IDIF and populated based input function (PBIF) can be used as input function of Patlak model to generate kinetic images which reveal biodistribution map of the metabolized molecule using indirect and direct methods.

6. Intended use

The uMI Panvivo is a PET/CT system designed for providing anatomical and functional images. The PET provides the distribution of specific radiopharmaceuticals. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for PET attenuation correction. PET and CT scans can be performed separately. The system is intended for assessing metabolic (molecular) and physiologic functions in various parts of the body, including the whole body, brain, head and neck, heart, lung, breast, gastrointestinal, urinary system and genital organ, musculoskeletal systems, and others organ or systems.

7. Indications for Use

The uMI Panvivo is a PET/CT system designed for providing anatomical and functional images. The PET provides the distribution of specific radiopharmaceuticals. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. PET and CT scans can be performed separately. The system is intended for assessing metabolic (molecular) and physiologic functions in various parts of the body. When used with radiopharmaceuticals approved by the regulatory authority in the country of use, the uMI Panvivo system generates images depicting the distribution of these radiopharmaceuticals. The images produced by the uMI Panvivo are intended for analysis and interpretation by qualified medical professionals. They can serve as an aid in detection, localization, evaluation, diagnosis, staging, re-staging, monitoring, and/or follow-up of abnormalities, lesions, tumors, inflammation, infection, organ function, disorders, and/or diseases, in several clinical areas such as oncology, cardiology, neurology, infection and inflammation. The images

produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

The CT system can be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.*

* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

8. Comparison of Technological Characteristics with the Predicate Device

uMI Panvivo employs the same basic operating principles and fundamental technologies, and has the similar indications for use as the predicate device. A comparison between the technological characteristics of proposed and predicate devices is provided as below.

Table 1 Comparison to Predicate device

ITEM	**Proposed Device uMI Panvivo**		**Predicate Device uMI Panvivo(K243538)**	
Model	**uMI Panvivo**	**uMI Panvivo S**	**uMI Panvivo**	**uMI Panvivo S**
Patient bore size	700mm	700mm	700mm	700mm
PET System	Scintillator material: LYSO Number of detector rings: • 100 Axial FOV: • 295 mm	Scintillator material: LYSO Number of detector rings: • 80 Axial FOV: • 235mm	Scintillator material: LYSO Number of detector rings: • 100 Axial FOV: • 295 mm	Scintillator material: LYSO Number of detector rings: • 80 Axial FOV: 235mm
CT System	uCT 780	uCT 780	uCT 780	uCT 780
Maximum table load	250kg	250kg	250kg	250kg
Software function				
Deep MAC	Yes	Yes	No	No
Digital Gating	Yes	Yes	No	No
OncoFocus	Yes	Yes	No	No
NeuroFocus	Yes	Yes	No	No
DEEPRECON.PET	Yes	Yes	No	No
uExcel DPR	Yes	Yes	No	No
ukinetics	Yes	Yes	No	No

uMI Panvivo's technological characteristics do not raise new safety and effectiveness concerns.

9. Performance Data

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

Non-Clinical Testing

Image performance test was conducted for uMI Panvivo to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device.

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

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI/AAMI ES60601-1: 2005/ (R) 2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012)[IncludingAmendment2(2021)]Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-3:2008+AMD1:2013+A2:2021, Edition 2.2, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-2-44:2009+A1:2012+A2:2016 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: 2014, Edition 3.0, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-6:2010+A1:2013+A2:2020, Edition 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 62304:2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes
- NEMA NU 2-2018, Performance Measurements of Positron Emission Tomographs
- IEC TR 60601-4-2:2016, Edition 1.0, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software

- NEMA PS 3.1-3.20(2023e): Digital Imaging and Communications in Medicine (DICOM)
- 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 10993-1:2018, Edition 5.0, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5: 2009, Edition 3.0, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: 2010, Edition 3.0, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Other Standards and Guidance

- ISO 14971: 2019, Edition 3.0, 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

Performance Verification

Non-clinical testing was conducted to verify the features described in this premarket submission.

- Various testing has been conducted (such as Deep MAC, Digital Gating, OncoFocus, NeuroFocus, DeepRecon.PET, uExcel DPR and uKinetics).
- Sample clinical images for Deep MAC, Digital Gating, OncoFocus, NeuroFocus, DeepRecon.PET, uExcel DPR and uKinetics were reviewed by U.S. board-certified radiologists. It was shown that the proposed device can generate images as intended and the image quality is sufficient for diagnostic use.

Summary of the Machine Learning Algorithm

- ***DeepRecon.PET***

DeepRecon.PET is an image post-processing technique which uses a pre-trained neural network to reduce noise and improve image quality.

The training dataset consists of image samples with different tracers, covering a wide and diverse range of clinical scenarios. Each subject underwent whole-body scanning on either the UIH uEXPLORER or uMI Panorama GS PET/CT system, both long axial field-of-view scanners with ultra-high sensitivity that ensures high image quality.

Ground-truth images were reconstructed from fully-sampled raw data. Training inputs were generated by reconstructing subsampled data at multiple down-sampling factors.

We have conducted validation on the uMI Panvivo and uMI Panvivo S system using both NEMA IQ phantoms and clinical patient cases. NEMA IQ phantoms data were acquired following the NEMA NU 2-2018 standard. For clinical evaluation, a total of 20 volunteers with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups (Table 2) were enrolled. The injected dose is in range of 1.29-11.6 mCi and the scan duration is in range of 8-24 min over 4-6 beds for whole-body scan and 5-10 min for brain scan. The testing data were down-sampled with different ratios and reconstructed with DeepRecon.PET and OSEM with Gaussian filtering.

Table 2 Distribution of volunteer dataset

Subjects' Characteristics (N=20)	**N(%)**
Gender, N(%)	
Male	13(65%)
Female	7(35%)
Age, N(%): Min=5, Max=79, Avg.=59.95, Std.=18.28	
0-29	1(5%)
30-49	5(25%)
50-69	7(35%)
>=70	7(35%)
Ethnicity, N(%)	
White	8(40%)
Asian	11(55%)
Black	1(5%)
Body Mass Index (BMI), N(%): Min=14.46, Max=40.51, Avg.=26.45, Std.=5.48	
Underweight (<18.5)	1(5%)
Healthy weight (18.5-24.9)	7(35%)
Overweight (25.0-29.9)	8(40%)
Obesity (>=30.0)	4(20%)

The testing datasets were collected from various clinical sites and were different from the training data. There is no overlap between the training data and the testing data and they are completely independent. No clinical subgroups and confounders have been defined for the datasets. The acceptance criteria for performance testing and the corresponding testing results can be found in Table 3.

Table 3 The performance evaluation report criteria of DeepRecon.PET

Evaluation Item	**Evaluation Method**	**Criteria**	**Results**

Image consistency	Measuring mean SUV of phantom background and liver ROIs (regions of interest) and calculating bias. It is used to evaluate image bias.	The bias is less than 5%.	Pass
Image background noise	a) Background variation (BV) in the IQ phantom. b) Liver and white matter signal to noise ratio (SNR) in the patient case. It is used to evaluate noise reduction performance.	DeepRecon.PET has lower BV and higher SNR than OSEM with Gaussian filtering.	Pass
Image contrast to noise ratio	a) Contrast to noise ratio (CNR) of the hot spheres in the IQ phantom. b) Contrast to noise ratio of lesions. CNR is a measure of the signal level in the presence of noise. It is used to evaluate lesion detectability.	DeepRecon.PET has higher CNR than OSEM with Gaussian filtering.	Pass

It is demonstrated that DeepRecon.PET can improve image SNR and lesion CNR while preserving image quantification consistency in spite of gender, ethnicities, age groups and BMIs variations. Meanwhile, test results also demonstrated that DeepRecon.PET has superior image SNR and lesion CNR compared to OSEM images reconstructed with fully sampled data as golden standards.
In addition, DeepRecon.PET images were evaluated by two American Board of Radiologists certificated physicians, covering a range of protocols and body parts (whole-body and brain part). The evaluation reports from radiologists verified that DeepRecon.PET meets the requirements of clinical diagnosis. All DeepRecon.PET images were rated as superior to OSEM with Gaussian filtering in terms of image contrast, image noise and image sharpness.

- ***uExcel DPR***

uExcel DPR is a PET reconstruction algorithm based on deep learning method. It utilizes pre-trained deep neural networks on long-axis datasets to optimize the iterative reconstruction process, effectively reducing noise and improving contrast. Compared to the conventional OSEM algorithm, the uExcel DPR can generate images with enhanced signal-to-noise ratio.

The high statistical properties of the PET data acquired by the Long Axial Field-of-View (LAFOV) PET/CT system enable the model to better learn image features. Therefore, the training dataset for the AI module in the uExcel DPR system is derived from the uEXPLORER and uMI Panorama GS PET/CT systems. Full-sampled data is used as the ground truth, while corresponding down-sampled data with varying down-

sampling factors serves as the training input. The validation dataset for uExcel DPR was derived from uMI Panvivo and uMI Panvivo S, comprising two NEMA IQ phantom datasets, two uniform cylindrical phantom datasets, and a clinical dataset from 19 human subjects. The NEMA IQ phantom scans were performed in compliance with NEMA NU 2-2018 standards. For the cylindrical phantom, a 10-minute acquisition was conducted at the scanner isocenter. Whole-body imaging protocols were applied for torso acquisition in human subjects, with total scan durations of 8-24 minutes over 4-6 bed positions. Brain imaging protocols were employed for cerebral data acquisition, requiring a 10-minute scan duration at a single bed position. Table 4 summarizes the demographic characteristics of the study cohort.

Table 4 The demographic distribution of human subjects

Subjects' Characteristics (N=19)	**N(%)**
Gender, N(%)	
Male	13(68.4%)
Female	6(31.6%)
Age, N(%)	
<18	1(5.3%)
18-40	3(15.8%)
41-65	9(47.3%)
>65	6(31.6%)
Ethnicity, N(%)	
White	7(36.8%)
Asian	11(57.9%)
Black	1(5.3%)
Body Mass Index (BMI), N(%)	
Underweight (<18.5)	1(5.3%)
Healthy weight (18.5-24.9)	10(52.5%)
Overweight (25.0-29.9)	4(21.1%)
Obesity (>=30.0)	4(21.1%)

The independence of these testing datasets was ensured by collecting testing data from various clinical sites and during separated time periods and on subjects different from the training data. Thus, the testing data have no overlap with the training data and are completely independent. No clinical subgroups and confounders have been defined for the datasets. The acceptance criteria for performance testing and the corresponding testing results can be found in Table 5.

Table 5 The performance evaluation report criteria of uExcel DPR

Evaluation Item	**Evaluation Method**	**Criteria**	**Results**
Quantitative evaluation	Contrast recovery (CR), background variability (BV), and contrast-to-noise ratio (CNR) were calculated using	The averaged CR, BV, and CNR of the uExcel DPR images should be superior to those of the OSEM images.	Pass

	NEMA IQ phantom data reconstructed with uExcel DPR and OSEM methods under acquisition conditions of 1 to 5 minutes per bed.		
	The Coefficient of Variation (COV) was calculated using uniform cylindrical phantom data on images reconstructed with both uExcel DPR and OSEM methods.	uExcel DPR requires fewer counts to achieve a matched COV compared to OSEM.	Pass
Qualitative evaluation	uExcel DPR images reconstructed at lower counts were qualitatively compared with full-count OSEM images.	uExcel DPR reconstructions with reduced count levels demonstrate comparable or superior image quality relative to higher-count OSEM reconstructions.	Pass

Bench testing demonstrated that, compared to the conventional OSEM algorithm, uExcel DPR achieves:

1) NEMA IQ Phantom Analysis: an average noise reduction of 81% and an average SNR enhancement of 391% were observed;
2) Uniform cylindrical Analysis: 1/10 of the counts can obtain the matching noise level.
3) Qualitative evaluation with human subjects: 1.7~2.5 MBq/kg radiopharmaceutical injection conditions, combined with 2~3 minutes whole-body scanning (4~6 bed positions), achieves comparable diagnostic image quality.

In addition, a blind comparison was conducted between images reconstructed using the uExcel DPR and OSEM algorithms. Two American board-certified nuclear medicine physicians were invited to evaluate the images independently. Clinical evaluation shows that all images are sufficient for clinical diagnosis, and images reconstructed using the uExcel DPR algorithm exhibit lower noise, better contrast, and superior sharpness compared to those reconstructed with the OSEM algorithm.

- ***OncoFocus***

OncoFocusis a motion correction technique to achieve respiratory motion artifacts correction. With the help of non-rigid image registration, it is capable of correcting motion effects, eliminating the activity-attenuation mismatch artifacts, as well as improving the accuracy of SUV and lesion volume.

There are two deep-learning-based AI networks in OncoFocus, one is the body cavity segmentation network (CNN-BC) for respiratory signal generation, and the other is the

attenuation map (umap) synthesis network (CNN-AC) for more accurate attenuation correction and image registration.

We have conducted validation on the uMI Panvivo and uMI Panvivo S system using clinical patient cases. A total of 50 volunteers with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups (Table 6) were enrolled. The cases underwent PET/CT scans 74.79±29.60 min post-injection of 213.53±45.68 MBq FDG, with 2min per bed position.

Table 6 Distribution of volunteer dataset

Subjects' Characteristics (N=50)	**N(%)**
Gender, N(%)	
Male	31(62%)
Female	19(38%)
Age, N(%): Min=34, Max=90, Avg.=72.7, Std.=11.9	
30-44	2(4%)
45-64	6(12%)
>=65	39(78%)
unkown	3(6%)
Ethnicity, N(%)	
White	34(68%)
Black	3(6%)
Asian	13(26%)
Body Mass Index (BMI), N(%): Min=15.1, Max=34.6, Avg.=24.0, Std.=3.8	
Underweight (<18.5)	2(4%)
Healthy weight (18.5-24.9)	24(48%)
Overweight (25.0-29.9)	23(46%)
Obesity (>=30.0)	1(2%)

The training dataset of the segmentation network (CNN-BC) and the mumap synthesis network(CNN-AC) in OncoFocus was collected from general clinical scenarios. Each subject was scanned by UIH PET/CT systems for clinical protocols. All the acquisitions ensure whole-body coverage. The input data of CNN-BC are CT-derived attenuation coefficient maps, and the target data of the network are body cavity region images. The input data are non-attenuation-corrected (NAC) PET reconstruction images, and the target data of the network are the reference CT attenuation coefficient maps.

The independence of these two networks' testing datasets was ensured by collecting testing data on cases different from the training data. Thus, the testing data have no overlap with the training data and are completely independent. No clinical subgroups and confounders have been defined for the datasets.

To validate the overall functionality of OncoFocus as an integrated system. The acceptance criteria for performance testing and the corresponding testing results can be found in Table 7.

Table 7 The performance evaluation report criteria of OncoFocus

Evaluation Item	Evaluation Method	Criteria	Results
Volume relative to no motion correction (ΔVolume).	Calculate the volume relative to no motion correction images	The ΔVolume value is less than 0%.	Pass
Maximal standardized uptake value relative to no motion correction (ΔSUVmax)	Calculate the SUVmax relative to no motion correction images	The ΔSUVmax value is large than 0%.	Pass

It is demonstrated that the average lesion volume of the OncoFocus images is smaller than that with no motion correction in spite of gender, ethnicities, age groups and BMIs variations. Meanwhile, the relative test results also showed the average lesion SUVmax of the OncoFocus images is superior to that with no motion correction.

In addition, the comparison between OncoFocus images and the related no motion correction images were evaluated by two American Board of Radiologists-certified physicians. The evaluation reports from radiologists verified that OncoFocus can reduce respiratory motion artifacts, yield higher PET/CT alignment accuracy, and enhance diagnostic confidence compared with the no motion correction images

- ***DeepMAC***

DeepMAC is an image post-processing technology that uses pre-trained neural networks to reduce metal artifacts and improve image quality.

The validation datasets of DeepMAC are from uMI Panvivo and uMI Panvivo S, including the PMMA phantom datasets and clinical dataset from 20 human subjects. A total of 20 volunteers with diverse demographic distributions covering various genders, age groups, ethnicity (Table 8) were enrolled.

Table 8 Distribution of volunteer dataset

Subjects' Characteristics (N=20)	N(%)

Gender, N(%)	
Male	12(60%)
Female	8(40%)
Age, N(%)	
0-29	1(5%)
30-49	1(5%)
50-69	9(45%)
>=70	9(45%)
Ethnicity, N(%)	
Caucasian	1(5%)
Asian	18(90%)
Negroid	1(5%)

The testing datasets were collected from various clinical sites and were different from the training data. There is no overlap between the training data and the testing data and they are completely independent. No clinical subgroups and confounders have been defined for the datasets. The acceptance criteria for performance testing and the corresponding testing results can be found in Table 9.

Table 9 The performance evaluation report criteria of DeepMAC

Evaluation Item	Evaluation Method	Criteria	Results
Quantitative evaluation	For PMMA phantom data, the average CT value in the affected area of the metal substance and the same area of the control image before and after DeepMAC was compared.	After using DeepMAC, the difference between the average CT value in the affected area of the metal substance and the same area of the control image does not exceed 10HU.	Pass

The experimental results show that this algorithm can effectively reduce metal artifacts. In addition, DeepMAC images were evaluated by two American Board of Radiologists certificated physicians. The evaluation reports from radiologists verified that DeepMAC effectively corrects metal artifacts and improves tissue interpretability.

Summary

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

10. Conclusions

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