July 28, 2026

Shanghai United Imaging Healthcare Co., Ltd.
Xin Gao
RA Manager
#2258 Chengbei Rd. Jiading District, 201807, Shanghai, China
Shanghai, 201807
China

Re: K261427
Trade/Device Name: uMI Panvivo (uMI Panvivo M)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 12, 2026
Received: June 12, 2026

Dear Xin Gao:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, Ph.D.
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.	K261427

Please provide the device trade name(s).

uMI Panvivo (uMI Panvivo M)

Please provide your Indications for Use below.

The system 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 system generates images depicting the distribution of these radiopharmaceuticals. The images produced by the system 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 (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510 (K) SUMMARY

K261427

1. Date of Preparation
June 12, 2026

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 M

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 Primary/Reference Device(s)

Predicate Device

510(k) Number: K251839
Device Name: uMI Panvivo S
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

Reference Device#1

510(k) Number: K241166
Device Name: uCT 550

Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

5. Device Description:

The proposed device uMI Panvivo M combines a 235 mm axial field of view (FOV) PET and 80-slice CT system to provide high quality functional and anatomical images, fast PET/CT imaging and better patient experience. The system includes PET system (identical to PET system of uMI Panvivo S cleared in K251839), CT system (similar to uCT 550 cleared in K241166), 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 PET system features the following specification and technologies.

- 700 mm patient bore size.
- LYSO detector with Axial Field of Views (AFOV) of 235 mm and corresponding imaging performances.
- 318 kg maximum table load capacity allows flexible positioning and access for all patients.
- HYPER Iterative (cleared in K251839), uses a regularized iterative reconstruction algorithm, which allows for more iterations while keeping the image noise at an acceptable level by incorporating a noise penalty term into the objective function.
- Ultra EFOV (cleared in K251839) is an extended field of view algorithm incorporating extrapolation and Deep Learning (DL). In this algorithm, Project domain extrapolation ensures the normal processing in convolution filter in scan field of view to reduce truncation artifact. DL technology using polar coordinate conversion in extending region can enhance the processing efficiency of deep networks and accelerate training test processing. Overall, AIEFOV does not affect the CT values accuracy inside of SFOV, and also increases the accuracy of CT values in the extended region.
- Deep MAC, Deep learning-based metal artifact correction (also named AI MAC, cleared in K251839) 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 K251839) 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) includes respiratory motion correction with full counts (RMC, cleared in K251839) and respiratory motion management with partial counts (RMM). RMC is a motion correction technique to achieve

respiratory motion artifacts correction. RMM is an amplitude-based respiratory gating technique to mitigate respiratory motion.

- NeuroFocus (also named HMC, cleared in K251839) 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 in K251839) uses a deep learning technique to produce better SNR (signal-to-noise-ratio) image in post-processing procedure.
- uExcel DPR (Deep Progressive Reconstruction, also named HYPER DPR or HYPER AiR, cleared in K251839) 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 in K251839) 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.

The main differences between uMI Panvivo M and uMI Panvivo S are the maximum table load, OncoFocus and CT sub-system. Oncofocus included in uMI Panvivo M adds respiratory motion management with partial counts (RMM) on the basis of respiratory motion correction with full counts (RMC). In addition, uMI Panvivo M can be installed either in medical facilities such as hospitals or on specific vehicles for frequent or infrequent transportation between different hospital sites or clinical imaging centers.

6. Intended use

The system 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 system 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 system generates images depicting the distribution of these radiopharmaceuticals. The images produced by the system 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 uMI 780. A comparison between the technological characteristics of proposed and predicate devices is provided as below.

ITEM	**Proposed Device**	**Predicate Device**
Model Name	**uMI Panvivo M**	**uMI Panvivo S (K251839)**
Patient Bore Size	700 mm	700 mm
Maximum Table Load	318 kg	250 kg
PET System	Scintillator material: LYSO Number of detector rings: 80 Axial FOV: 235mm	Scintillator material: LYSO Number of detector rings: 80 Axial FOV: 235mm
	OncoFocus (RMC& RMM)	OncoFocus (RMC)
CT System	Similar to uCT 550(K241166), modified CT	Identical to uCT 780(K241079)

	sub-system to be installed on fixed site or vehicles.	

uMI Panvivo M'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 M 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 2-2024, Performance Measurements of Positron Emission Tomographs
- IEC TR 60601-4-2:2024, 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(2024e): 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: 2021, 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.

- Performance tests for HYPER Iterative, NeuroFocus, Ultra EFOV, OncoFocus, uExcel DPR, Deep MAC, Digital gating, uKinetics and DeepRecon.PET.
- Sample clinical images for General, HYPER Iterative, Ultra EFOV, OncoFocus, NeuroFocus, uExcel DPR, Deep MAC and DeepRecon.PET of new models were reviewed by U.S. board-certified radiologists.

Summary of the Machine Learning Algorithm

- ***DeepMAC***

DeepMAC is an image post-processing technology that uses pre-trained neural networks to reduce metal artifacts and improve image quality. The training data is derived from system simulations and contains pairs of image data: on the one hand, images with metal artifacts, and on the other hand, corresponding ground truth images without metal artifacts.

The validation datasets of DeepMAC are including the PMMA phantom datasets and clinical dataset consisting of 1561 images. A total of 20 humans with diverse

demographic distributions covering various genders, age groups, ethnicity (Table 1) were enrolled.

Table 1 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 2.

Table 2 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.

uExcel DPR

uExcel DPR (Deep Progressive Reconstruction) is a deep learning-based PET reconstruction algorithm. It utilizes pre-trained deep neural networks on long-axis datasets to optimize the iterative reconstruction process, effectively reducing noise and improving contrast. In comparison to the conventional OSEM algorithm, uExcel DPR achieves a higher signal-to-noise ratio in generated images.

The training dataset for the AI model in uExcel DPR is sourced from the uEXPLORER and uMI Panorama GS PET/CT systems. 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. Full-sampled data serves as the ground truth, while corresponding down-sampled data, created with varying down-sampling factors, acts as the training input. The validation dataset for uExcel DPR was collected from uMI Panvivo M, comprising a NEMA IQ phantom data and a clinical dataset of 74 human studies. The NEMA IQ phantom scans were performed in compliance with NEMA NU 2-2018 standards. Whole-body imaging protocols were applied for human subjects, with total scan durations of 10-24 minutes over 5-12 bed positions. Brain imaging protocols required a 5-minute scan duration at a single bed position. Table 3 summarizes the demographic characteristics of the study cohort.

Table 3 The demographic distribution of human subjects

Studies' Characteristics (N=74)	**N(%)**
Gender, N(%)	
Male	21 (28.4%)
Female	53 (71.6%)
Age, N(%)	
30-60	26 (35.1%)
>60	48 (64.9%)
Ethnicity, N(%)	
Asian	63 (85.1%)
White	6 (8.1%)
Black	5 (6.8%)
Body Mass Index (BMI), N(%)	
Healthy weight (18.5-24.9)	26 (35.1%)
Overweight (25.0-29.9)	17 (23.0%)
Obesity (30.0-39.9)	31 (41.9%)

The testing data are entirely independent from the training data, as they were collected using different types of PET/CT scanners. Furthermore, there are no defined clinical subgroups or confounders for either dataset. The acceptance criteria for performance testing, along with the corresponding testing results, are presented in Table 4.

Table 4 The performance evaluation report criteria of uExcel DPR

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

	OSEM under acquisition conditions of 1 to 5 minutes per bed.		
Human subject evaluations	A comparative evaluation of uExcel DPR and OSEM reconstructed images was conducted through independent visual assessments and quantitative liver signal-to-noise ratio (liverSNR) analyses.	uExcel DPR demonstrate superior image SNR compared to OSEM reconstruction across various counting conditions.	Pass

Benchmark testing demonstrated that uExcel DPR surpasses the conventional OSEM algorithm in the following areas:

1) NEMA IQ Phantom Analysis: A maximum noise reduction of 69% and an average SNR improvement of 207%;

3) Human subject evaluations: Superior image SNR across diverse counting conditions.

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 demonstrated that all images were adequate for clinical diagnosis, with images reconstructed using the uExcel DPR algorithm exhibiting lower noise, improved contrast, and greater sharpness compared to those reconstructed with the OSEM algorithm.

- ***OncoFocus***

OncoFocus includes respiratory motion correction with full counts (RMC) and respiratory motion management with partial counts (RMM).

RMC is 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.

RMM is an amplitude-based respiratory gating technique to mitigate respiratory motion. A user-specified fraction of the total acquired counts is selected for subsequent image reconstruction. By using only data acquired during minimal respiratory motion, this approach effectively reduces image blurring and artifacts induced by respiratory movement.

There are two deep-learning-based AI networks in RMC and RMM, one is the body cavity segmentation network (CNN-SEG) for respiratory signal generation, and the other is the attenuation map (μmap) synthesis network (CNN-AC) for more accurate attenuation correction and image registration.

We have conducted validation on the uMI Panvivo M system using clinical patient cases. A total of 13 scans with diverse demographic distributions covering various genders, age groups, and BMI groups (Table 5) were enrolled. The cases underwent PET/CT scans 65.38±17.31 min post-injection of 213.21±104.56 MBq FDG and non FDG, with 1min30s per bed position.

Table 5 Distribution of volunteer dataset

Subjects' Characteristics (N=13)	**N(%)**
Gender, N(%)	
Male	5(38%)
Female	8(62%)
Age, N(%): Min=31, Max=81, Avg.=57.2, Std.=16.4	
30-44	5(38%)
45-64	3(23%)
>=65	5(38%)
Ethnicity, N(%)	
Asian	13(100%)
Body Mass Index (BMI), N(%): Min=18.4, Max=30.4, Avg.=25.6, Std.=3.7	
Underweight (<18.5)	1(8%)
Healthy weight (18.5-24.9)	4(31%)
Overweight (25.0-29.9)	7(54%)
Obesity (>=30.0)	1(8%)

The training dataset of the segmentation network (CNN-SEG) and the μmap synthesis network (CNN-AC) in RMC and RMM 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-SEG 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 RMC and RMM as an integrated system. The acceptance criteria for performance testing and the corresponding testing results can be found in Table 6

Table 6 The performance evaluation report criteria of RMC and RMM

Evaluation Item	**Evaluation Method**	**Criteria**	**Results**
Volume relative to no respiratory motion correction (ΔVolume).	Calculating the RMC and RMM volume change relative to no respiratory motion correction images	The ΔVolume value is less than 0%.	Pass
Maximal standardized uptake value relative to no respiratory motion correction (ΔSUVmax)	Calculating the SUVmax obtained from the RMC and RMM with that from the corresponding non-corrected image	The ΔSUVmax value is large than 0%.	Pass

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

In addition, the comparison between RMC and RMM images and the related NMC (non-motion correction) images was evaluated by two American Board of Radiologists-certified physicians. The evaluation reports from radiologists verified that RMC and RMM can reduce respiratory motion artifacts and enhance diagnostic confidence compared with the NMC images.

- ***Ultra EFOV***

  Ultra EFOV, which is also known as AI EFOV. The training data consists of clinical data with different patient body sizes and different scanning positions. All data were manually quality controlled before included for training.

  The performance bench tests include:
  - water phantom scan in the center and outside of CT scan-FOV
  - patient studies in the center and outside of CT scan-FOV

The acceptance criteria of performance bench tests were:

- Ultra EFOV shall improve the accuracy of CT value, and improve the accuracy and uniformity of PET image SUV by performing attenuation correction with CT generated with Ultra EFOV algorithm when scanned object exceed CT field of view.
- Ultra EFOV shall have consistent CT value, and PET image SUV by performing attenuation correction with CT generated with Ultra EFOV algorithm when scanned object does not exceed the CT field of view.

The input and output for the algorithm training were both derived from system simulations based on the same patient. The simulated gold standard used as the network output consists of images free from truncation artifacts. In contrast, the input to the network consists of images reconstructed with truncation artifacts, generated by reconstructing from data where both sides of the detector have been truncated. Consequently, this algorithm does not require manual annotation.

Besides the performance bench tests, a clinical evaluation was also performed. The clinical test dataset included 3370 images of 2 patients (Table 7) at different truncation situations were scanned to prove the effectiveness of Ultra EFOV.

Table 7 Distribution of volunteer dataset

Subjects' Characteristics (N=2)	**N(%)**
Gender, N(%)	
Male	1 (50.0%)
Female	1 (50.0%)
Age, N(%): Min=35 Max=73, Avg.=57.3, Std.=16.4	
20-44	0 (25.0%)
45-64	1 (25.0%)
>=65	1 (50.0%)
Ethnicity, N(%)	
Asian	2 (100%)
Body Mass Index (BMI), N(%): Min=26.1, Max=28.3, Avg.=27.3, Std.=0.9	
Healthy weight (18.5-24.9)	0 (0%)
Overweight (25.0-29.9)	1 (50.0%)
Obesity (>=30.0)	1 (50.0%)

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 8.

Table 8 The performance evaluation report criteria of Ultra EFOV

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

Quantitative evaluation	For phantom study, the water phantom outside of CT scan-FOV was tested to compare the Ultra EFOV algorithm with EFOV algorithm. For patient study, the SUV of some ROIs in PET image with attenuation correction performed with CT generated with EFOV and Ultra EFOV algorithm will be compared.	Compared to the ground truth, the uniformity and SUV deviation of PET image obtained by using Ultra EFOV for attenuation correction should be less than 5%. And when the scanned object does not exceed the CT field of view, attenuation correction using CT generated either with Ultra EFOV or EFOV should result in consistent PET image SUV.	Pass

Bench tests showed that performing attenuation correction with CT images generated with Ultra EFOV can improve the accuracy of SUV, in cases where the scanned object exceeds the CT scan-FOV. Meanwhile, when the scanned object does not exceed the CT scan-FOV, attenuation correction using CT generated with either Ultra EFOV or EFOV results in consistent SUV. Clinical evaluation concluded Ultra EFOV has the potential to enhance homogeneity and reduce image artifacts.

- ***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 tens of millions of clinical image patches with different tracers from diverse clinical sites, 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 M system using both NEMA IQ phantom and 66 clinical patient studies. NEMA IQ phantom data were acquired following the NEMA NU 2-2018 standard. Volunteers with diverse demographic distributions covering various genders, age groups, ethnicity, and BMI groups (Table 9) were enrolled. The injected dose is in range of 2.65-8.57 mCi and the scan duration is in range of 10-16 min over 5-8 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 9 Distribution of volunteer dataset

Subjects' Characteristics (N=66)	**N(%)**
Gender, N(%)	
Male	42(64%)
Female	24(36%)
Age, N(%)	
0-35	6(9.1%)
35-55	18(27.3%)
55-75	24(36.3%)
>=75	18(27.3%)
Ethnicity, N(%)	
Asian	54(82%)
White	6(9%)
Black	6(9%)
Body Mass Index (BMI), N(%)	
Healthy weight (18.5-24.9)	24(36.3%)
Overweight (25.0-29.9)	24(36.3%)
Obesity (>=30.0)	18(27.4%)

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 10.

Table 10 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 noise and overall image quality.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uMI Panvivo M 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.