



April 3, 2026

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

Re: K260524

Trade/Device Name: uMI Panvivo (uMI Panvivo LS);  
uMI Panvivo (uMI Panvivo);  
uMI Panvivo (uMI Panvivo S);  
uMI Panvivo (uMI Panvivo EX);  
uMI Panvivo (uMI Panvivo ES)

Regulation Number: 21 CFR 892.1200

Regulation Name: Emission Computed Tomography System

Regulatory Class: Class II

Product Code: KPS, JAK

Dated: February 16, 2026

Received: February 17, 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/pmnmn.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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue watermark of the letters 'FDA'.

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.

K260524

?

Please provide the device trade name(s).

?

uMI Panvivo (uMI Panvivo LS);  
uMI Panvivo (uMI Panvivo);  
uMI Panvivo (uMI Panvivo S);  
uMI Panvivo (uMI Panvivo EX);  
uMI Panvivo (uMI Panvivo ES)

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**

K260524

**1. Date of Preparation**

March 3, 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, uMI Panvivo S, uMI Panvivo ES, uMI Panvivo EX, uMI Panvivo LS

**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:** K253564

**Device Name:** uMI Panvivo

**Regulation Name:** Emission Computed Tomography System

**Regulatory Class:** II

**Product Code:** KPS, JAK

**Review Panel:** Radiology

**5. Device Description:**

The proposed device uMI Panvivo combines a 295/235/534/712/1069 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 K253564. The main modifications performed on the uMI Panvivo (K253564) in this submission are the addition of one new model. The previous uMI Panvivo (K253564) is designed with scalable PET rings; uMI Panvivo LS is scaling to 360 PET rings, compares to the uMI Panvivo 100 PET rings, uMI Panvivo S 80 PET rings, uMI Panvivo ES 180 PET rings and uMI Panvivo EX 240 PET rings.

## **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**

The proposed uMI Panvivo employ the same basic operating principles and fundamental technologies, and have same indications for use as predicate devices. 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 (K253564)				Remark
Model		uMI Panvivo LS	uMI Panvivo ES	uMI Panvivo EX	uMI Panvivo	uMI Panvivo S	
<b>Detector</b>	Scintillator material	LYSO	LYSO	LYSO	LYSO	LYSO	Same
	Scintillator dimensions	2.76mm×2.76mm× 18.1mm	2.76mm×2.76mm× 18.1mm	2.76mm×2.76mm× 18.1mm	2.76mm×2.76mm× 18.1mm	2.76mm×2.76mm× 18.1mm	Same
	Detector ring diameter	734	734	734	734	734	Same
	Number of detector rings	360	180	240	100	80	Note 1
	Axial field of view	1069mm	534mm	712mm	295 mm	235 mm	
	Coincidence window	4.9ns	4.9ns	4.9ns	4.6ns	4.6ns	Same
<b>Spatial Resolution</b>	Axial FWHM@1cm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	Same
	Radial FWHM @1cm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	
	Tangential FWHM @1cm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	
	Axial FWHM@10cm	< 4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	
	Radial FWHM @1cm	< 4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	

	Tangential FWHM@10cm	< 4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	
	Axial FWHM@20cm	< 5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	
	Radial FWHM @20cm	< 5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	
	Tangential FWHM@20cm	< 5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	
<b>Sensitivity</b>		> 142cps/kBq	> 48cps/kBq	> 85cps/kBq	> 16cps/kBq	> 10cps/kBq	Note 2
<b>NECR Peak Value</b>		> 2500kcps	> 900kcps	> 1550cps	> 300kcps	> 200kcps	Note 3
<b>Peak True Count Rate</b>		> 2000kcps	> 2000kcps	> 2000kcps	> 1500kcps	> 800kcps	
<b>PET Scatter Fraction</b>		< 0.42	< 0.42	< 0.42	< 0.42	< 0.42	Same
<b>Accuracy (absolute value)</b>		< 5%	< 5%	< 5%	< 5%	< 5%	Same
<b>Image Quality</b>		Contrast Recovery 10 mm Sphere > 45.0%	Contrast Recovery 10 mm Sphere > 45.0%	Contrast Recovery 10 mm Sphere > 45.0%	Contrast Recovery 10 mm Sphere > 45.0%	Contrast Recovery 10 mm Sphere > 45.0%	Same
		13 mm Sphere > 55.0%	13 mm Sphere > 55.0%	13 mm Sphere > 55.0%	13 mm Sphere > 55.0%	13 mm Sphere > 55.0%	
		17 mm Sphere > 65.0%	17 mm Sphere > 65.0%	17 mm Sphere > 65.0%	17 mm Sphere > 65.0%	17 mm Sphere > 65.0%	

22 mm Sphere > 72.0%	22 mm Sphere > 72.0%	22 mm Sphere > 72.0%	22 mm Sphere > 72.0%	22 mm Sphere > 72.0%
28 mm Sphere > 65.0%	28 mm Sphere > 65.0%	28 mm Sphere > 65.0%	28 mm Sphere > 65.0%	28 mm Sphere > 65.0%
37 mm Sphere > 70.0%	37 mm Sphere > 70.0%	37 mm Sphere > 70.0%	37 mm Sphere > 70.0%	37 mm Sphere > 70.0%
Lung Residual error < 8.0%	Lung Residual error < 8.0%	Lung Residual error < 8.0%	Lung Residual error < 8.0%	Lung Residual error < 8.0%
Background variability	Background variability	Background variability	Background variability	Background variability
10mm Sphere < 7.5%	10mm Sphere < 7.5%	10mm Sphere < 7.5%	10mm Sphere < 7.5%	10mm Sphere < 7.5%
13mm Sphere < 7.0%	13mm Sphere < 7.0%	13mm Sphere < 7.0%	13mm Sphere < 7.0%	13mm Sphere < 7.0%
17mm Sphere < 7.0%	17mm Sphere < 7.0%	17mm Sphere < 7.0%	17mm Sphere < 7.0%	17mm Sphere < 7.0%
22mm Sphere < 7.0%	22mm Sphere < 7.0%	22mm Sphere < 7.0%	22mm Sphere < 7.0%	22mm Sphere < 7.0%
28mm Sphere < 7.0%	28mm Sphere < 7.0%	28mm Sphere < 7.0%	28mm Sphere < 7.0%	28mm Sphere < 7.0%
37mm Sphere < 7.0%	37mm Sphere < 7.0%	37mm Sphere < 7.0%	37mm Sphere < 7.0%	37mm Sphere < 7.0%

<b>Time-of-flight Resolution</b>	< 245 ps	< 245 ps	< 245 ps	< 245 ps	< 245 ps	Same
<b>PET-CT Coregistration Accuracy</b>	< 3.0 mm	< 3.0 mm	< 3.0 mm	< 3.0 mm	< 3.0 mm	Same
<b>Table Maximum table load</b>	280kg	280kg	280kg	280kg	280kg	Same
<b>Advanced Function</b>						
<b>Deep MAC</b>	Yes	Yes	Yes	Yes	Yes	Same
<b>Digital Gating</b>	Yes	Yes	Yes	Yes	Yes	Same
<b>OncoFocus</b>	Yes	Yes	Yes	Yes	Yes	Same
<b>NeuroFocus.Brain</b>	Yes	Yes	Yes	No	No	Note 4
<b>uExcel DPR</b>	Yes	Yes	Yes	Yes	Yes	Note 5
<b>uKinetics</b>	Yes	Yes	Yes	Yes	Yes	Same
<b>Ultra EFOV</b>	Yes	Yes	Yes	Yes	Yes	Same
<b>HYPER Iterative</b>	Yes	Yes	Yes	Yes	Yes	Same

<b>Justification</b>	
Note 1	The number of detector rings and the axial Field of View (aFOV) of the proposed devices are larger than that of the predicate devices. A longer aFOV can increase the scanning range per bed position, thereby reducing the number of bed positions required for a whole-body scan and shortening the total scanning time. The differences do not affect the clinical effectiveness and safety.
Note 2	The Sensitivities of the proposed devices are larger than that of the predicate devices. Improved system sensitivity enables the acquisition of more counts under identical scan duration and radiotracer activity, which in turn leads to better image quality. The difference does not raise new safety and effectiveness concerns.
Note 3	The proposed devices provide larger NECR peak value and Peak True Count Rate to the Predicate devices. The higher NECR Peak Value and Peak True Count Rate will let system acquire more effective data even in high activity concentration. The difference does not raise new safety and effectiveness concerns.
Note 4	NeuroFocus.Brain is a brain-artifact elimination solution that employs a statistics-based motion detection method to automatically select an optimal motion-free subset of counts for reconstruction. The previous long-axial PET systems uMI Panvivo EX and uMI Panvivo ES already cleared with NeuroFocus.Brain, NeuroFocus.Brain in uMI Panvivo LS is same with the previous uMI Panvivo EX and uMI Panvivo ES. Performance test was conducted on the proposed device. It didn't raise any new safety and effectiveness concerns.
Note 5	The uExcel DPR implemented on the uMI Panvivo LS systems is algorithmically identical to the previously cleared uExcel DPR feature on the uMI Panvivo systems (K253564). uMI Panvivo LS has the same intended use with uMI Panvivo ES and uMI Panvivo EX, which means it only supports FDG ( <sup>18</sup> F-FDG) while uMI Panvivo and uMI Panvivo S supports several imaging agents. Performance test and clinical image evaluation were conducted on the proposed device. It is shown that the difference did 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(2

- 021)]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(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: 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.

- Performance tests for HYPER Iterative, Ultra EFOV, OncoFocus, NeuroFocus.Brain, uExcel DPR, Deep MAC, Digital gating and uKinetics.
- Sample clinical images for General, HYPER Iterative, OncoFocus and uExcel DPR of new models were reviewed by U.S. board-certified radiologists. It was shown that the proposed models can generate images as intended and the image quality is sufficient for diagnostic use.

### 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 2) were enrolled.

Table 2 Distribution of volunteer dataset

Subjects' Characteristics (N=20)	N(%)
<b>Gender, N(%)</b>	
Male	12(60%)
Female	8(40%)
<b>Age, N(%)</b>	
0-29	1(5%)
30-49	1(5%)
50-69	9(45%)
>=70	9(45%)
<b>Ethnicity, N(%)</b>	
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 3.

Table 3 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 LS, comprising a NEMA IQ phantom data and a clinical dataset of 27 human studies. The NEMA IQ phantom scans were performed in compliance with NEMA NU 2-2018 standards. Total-body imaging protocols were applied for human subjects, with total scan durations of 4-6 minutes over 2 bed positions. Brain imaging protocols required a 5-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

Studies' Characteristics (N=27)	N(%)
<b>Gender, N(%)</b>	
Male	7 (25.9%)
Female	20 (74.1%)
<b>Age, N(%)</b>	
30-60	26 (96.3%)
>60	1 (3.7%)
<b>Ethnicity, N(%)</b>	
Asian	27 (100%)
<b>Body Mass Index (BMI), N(%)</b>	

Healthy weight (18.5-24.9)	16 (59.3%)
Overweight (25.0-29.9)	11 (40.7%)

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 5.

Table 5 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 OSEM under acquisition conditions of 1 to 5 minutes per bed.	The averaged CR, BV, and CNR of the uExcel DPR images should be superior to those of the OSEM images.	Pass
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 65% and an average SNR improvement of 152%;
- 2) 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 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.

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

We have conducted validation on the uMI Panvivo LS system using clinical patient cases. A total of 15 scans with diverse demographic distributions covering various genders, age groups, and BMI groups (Table 6) were enrolled. The cases underwent PET/CT scans  $65.45 \pm 33.28$  min post-injection of  $217.32 \pm 84.79$  MBq FDG, with 2~5 min per bed position.

Table 6 Distribution of volunteer dataset

<b>Subjects' Characteristics (N=15)</b>	<b>N(%)</b>
<b>Gender, N(%)</b>	
Male	11(73%)
Female	4(27%)
<b>Age, N(%)</b> : Min=36, Max=78, Avg.=63.1, Std.=11.9	
30-44	1(7%)
45-64	4(27%)
>=65	10(67%)
<b>Ethnicity, N(%)</b>	
Asian	15(100%)
<b>Body Mass Index (BMI), N(%)</b> : Min=16.8, Max=30.8, Avg.=23.0, Std.=3.5	
Underweight (<18.5)	1(7%)
Healthy weight (18.5-24.9)	12(80%)
Overweight (25.0-29.9)	1(7%)
Obesity (>=30.0)	1(7%)

The training dataset of the segmentation network (CNN-SEG) 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-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 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

<b>Evaluation Item</b>	<b>Evaluation Method</b>	<b>Criteria</b>	<b>Results</b>
Volume relative to no respiratory motion correction ( $\Delta$ Volume).	Calculating the OncoFocus volume change relative to no respiratory motion correction images	The $\Delta$ Volume value is less than 0%.	Pass
Maximal standardized uptake value relative to no respiratory motion correction ( $\Delta$ SUVmax)	Calculating the SUVmax obtained from the OncoFocus with that from the corresponding non-corrected image	The $\Delta$ SUVmax 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, 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 NMC (non-motion correction) images was 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 NMC images.

● **NeuroFocus.Brain**

NeuroFocus.Brain is a motion management technology that incorporates AI in certain steps to help eliminate head artifacts in brain PET imaging. It employs an end-to-end, data-driven workflow that automatically detects motion without manual parameter tuning. By analyzing the centroid-of-distribution (COD) of brain activity over time, the system identifies motion moments and selects the optimal contiguous motion-free data segment for reconstruction.

The solution integrates two deep learning networks: a brain segmentation network (CNN-SEG) for robust motion signal extraction, and a CNN-based attenuation map synthesis network (CNN-AC, applicable to FDG only) for improved  $\mu$ -map estimation and image alignment. For non-FDG scans, the CT-based  $\mu$ -map is used directly. Together, these approaches enable precise motion management, reduce blurring, and enhance diagnostic confidence in clinical brain PET/CT imaging.

The validation on the new uMI Panvivo LS system features an enhanced clinical dataset of 24 scans, including motion-corrupted, motion-free, and critically, a motion-guided paired acquisition that provides a direct ground truth. Detailed gender, age, ethnicity, and BMI group information for these 24 scans is summarized in Table 8.

Table 8 Distribution of volunteer dataset

<b>Subjects' Characteristics (N=24)</b>	<b>N(%)</b>
<b>Gender, N(%)</b>	
Male	13(54.2%)
Female	11(45.8%)
<b>Age, N(%)</b> : Min=29 Max=74, Avg.=58.5, Std.=12.7	
20-44	5(20.8%)
45-64	8(33.3%)
>=65	11(45.8%)
<b>Ethnicity, N(%)</b>	
Asian	24(100%)
<b>Body Mass Index (BMI), N(%)</b> : Min=20.5, Max=30.8, Avg.=24.9, Std.=2.7	
Healthy weight (18.5-24.9)	14(58.3%)
Overweight (25.0-29.9)	8(33.3%)
Obesity (>30.0)	2(8.3%)

The training dataset of the brain segmentation network (CNN-SEG) and the mumap synthesis network (CNN-AC) in NeuroFocus.Brain was collected from general clinical scenarios. Each subject was scanned by UIH PET/CT systems for clinical protocols. All the acquisitions ensure whole head coverage. The input data of brain segmentation network are CT-derived attenuation coefficient maps, and the target data of the network are brain region images. For CNN-AC, 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 the testing datasets for these two networks was ensured by collecting testing data on a scanner that was different from the one used for the training data, thereby guaranteeing complete separation between the training and testing datasets. 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 NeuroFocus.Brain

<b>Evaluation Item</b>	<b>Evaluation Method</b>	<b>Criteria</b>	<b>Results</b>
------------------------	--------------------------	-----------------	----------------

motion-guided paired data	Compare SUVmean in the high-uptake region of the prefrontal cortex between NeuroFocus.Brain reconstruction and ground truth	$ \Delta SUV_{mean}  < 10\%$	Pass
	Compare SUVmean in the high-uptake region of the prefrontal cortex of the motion scan between NeuroFocus.Brain reconstruction and conventional reconstruction	$\Delta SUV_{mean} > 5\%$	Pass
motion-corrupted data	Compare SUVmean in the high-uptake region of the prefrontal cortex between NeuroFocus.Brain and conventional reconstruction	$\Delta SUV_{mean} > 0\%$	Pass
motion-free data	Compare SUVmean in the high-uptake region of the prefrontal cortex between NeuroFocus.Brain and conventional reconstruction	$ \Delta SUV_{mean}  < 10\%$	Pass

It is demonstrated that NeuroFocus.Brain could effectively correct the quantitative reduction in high-uptake regions caused by head motion, restoring the values to levels comparable to those in the absence of head motion. The results indicate that NeuroFocus.Brain significantly improves quantitative accuracy in cases with head motion.

● **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 10) at different truncation situations were scanned to prove the effectiveness of Ultra EFOV.

Table 10 Distribution of volunteer dataset

Subjects' Characteristics (N=2)	N(%)
<b>Gender, N(%)</b>	
Male	1 (50.0%)
Female	1 (50.0%)
<b>Age, N(%)</b> : Min=35 Max=73, Avg.=57.3, Std.=16.4	
20-44	0 (25.0%)
45-64	1 (25.0%)
>=65	1 (50.0%)
<b>Ethnicity, N(%)</b>	
Asian	2 (100%)
<b>Body Mass Index (BMI), N(%)</b> : 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)	2 (100.0%)
Obesity (>=30.0)	0 (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 11.

Table 11 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.

### **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.