February 13, 2026

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

Re: K253564
Trade/Device Name: 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: December 29, 2025
Received: December 29, 2025

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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253564

Device Name
uMI Panvivo (uMI Panvivo); uMI Panvivo (uMI Panvivo S); uMI Panvivo (uMI Panvivo EX); uMI Panvivo (uMI Panvivo ES)

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510 (K) SUMMARY K253564

1. **Date of Preparation**
   January 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, uMI Panvivo S, uMI Panvivo ES, uMI Panvivo EX

   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: K251839
   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 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 K251839.The main modifications performed on the uMI Panvivo (K251839) in this submission are the addition of two new models. The previous uMI Panvivo(K251839) is designed with scalable PET rings; uMI Panvivo ES is scaling to 180 PET rings and uMI Panvivo EX is scaling to 240 PET rings, compares to the uMI Panvivo 100 PET rings and uMI Panvivo S 80 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(K251839)		Remark
Model		uMI Panvivo	uMI Panvivo S	uMI Panvivo ES	uMI Panvivo EX	uMI Panvivo	uMI Panvivo S	
Detector	Scintillator material	LYSO	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	2.76mm×2.76mm×18.1mm	Same
	Detector ring diameter	734	734	734	734	734	734	Same
	Number of detector rings	100	80	180	240	100	80	Note 1
	Axial field of view	295 mm	235 mm	534mm	712mm	295 mm	235 mm	
	Coincidence window	4.6ns	4.6ns	4.9ns	4.9ns	4.6ns	4.6ns	Note 2
Spatial Resolution	Axial FWHM@1cm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	Same
	Radial FWHM @1cm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	
	Tangential FWHM @1cm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	< 3.5mm	
	Axial FWHM@10cm	≤4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	≤4.0mm	< 4.0mm	
	Radial FWHM @1cm	≤4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	≤4.0mm	< 4.0mm	
	Tangential FWHM@10cm	≤4.0mm	< 4.0mm	< 4.0mm	< 4.0mm	≤4.0mm	< 4.0mm	

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	Axial FWHM@20cm	≤5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	≤5.0mm	< 5.0mm	
	Radial FWHM @20cm	≤5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	≤5.0mm	< 5.0mm	
	Tangential FWHM@20cm	≤5.0mm	< 5.0mm	< 5.0mm	< 5.0mm	≤5.0mm	< 5.0mm	
Sensitivity		> 16cps/kBq	> 10cps/kBq	> 48ps/kBq	> 85ps/kBq	> 16cps/kBq	> 10cps/kBq	Note 3
NECR Peak Value		> 300kcps	> 200kcps	> 900kcps	> 1550cps	> 300kcps	> 200kcps	Note 4
Peak True Count Rate		> 1500kcps	> 800kcps	> 2000kcps	> 2000kcps	> 1500kcps	> 800kcps	
PET Scatter Fraction		< 0.42	< 0.42	< 0.42	< 0.42	< 0.42	< 0.42	Same
Accuracy (absolute value)		< 5%	< 5%	< 5%	< 5%	< 5%	< 5%	Same
Image Quality		Contrast Recovery 10 mm Sphere > 45.0% 13 mm Sphere > 55.0% 17 mm Sphere > 65.0%	Contrast Recovery 10 mm Sphere > 45.0% 13 mm Sphere > 55.0% 17 mm Sphere > 65.0%	Contrast Recovery 10 mm Sphere > 45.0% 13 mm Sphere > 55.0% 17 mm Sphere > 65.0%	Contrast Recovery 10 mm Sphere > 45.0% 13 mm Sphere > 55.0% 17 mm Sphere > 65.0%	Contrast Recovery 10 mm Sphere > 45.0% 13 mm Sphere > 55.0% 17 mm Sphere > 65.0%	Contrast Recovery 10 mm Sphere > 45.0% 13 mm Sphere > 55.0% 17 mm Sphere > 65.0%	Same

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

Time-of-flight Resolution	< 245 ps	< 245 ps	< 245 ps	< 245 ps	< 245 ps	< 245 ps	Same
PET-CT Coregistration Accuracy	< 3.0 mm	< 3.0 mm	< 3.0 mm	< 3.0 mm	< 3.0 mm	< 3.0 mm	Same
Table Maximum table load	280kg	280kg	280kg	280kg	250kg	250kg	Note 5
Advanced Funciton							
Deep MAC	Yes	Yes	Yes	Yes	Yes	Yes	Same
Digital Gating	Yes	Yes	Yes	Yes	Yes	Yes	Same
OncoFocus	Yes	Yes	Yes	Yes	Yes	Yes	Same
NeuroFocus.Brain	No	No	Yes	Yes	No	No	Note 6
uExcel DPR	Yes	Yes	Yes	Yes	Yes	Yes	Note 7
ukinetics	Yes	Yes	Yes	Yes	Yes	Yes	Same
AI EFOV	Yes	Yes	Yes	Yes	Yes	Yes	Same
HYPER Iterative	Yes	Yes	Yes	Yes	Yes	Yes	Same
Intelligent Assistant	No	No	Yes	Yes	No	No	Note8

Justification	
Note 1	The number of detector rings and the axial Field of View (aFOV) of the poposed 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	For systems with a longer aFOV, the coincidence timing window was increased based on simulation analyses to accommodate the detection of more LORs (Line of Response). This adjustment is moderate and well-controlled, and does not affect the system's Image Quality (IQ) performance. The difference does not affect the clinical effectiveness and safety.
Note 3	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 4	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 5	Following system tests that confirmed the table's ability to support a 280 kg load, the maximum load specification has been increased. This revision is justified, as the original specifications included an excessive safety margin, with no changes to the bed's design. The difference does not raise new safety and effectiveness concerns.
Note 6	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 long-axial PET systems (uMI Panvivo EX and uMI Panvivo ES), unlike the previously cleared short-axial uMI Panvivo and uMI Panvivo S, provide inherently higher native sensitivity that compensates for the discarded counts. The exclusive use of the optimal subset improves reconstruction efficiency. Performance and clinical image evaluation were conducted on the proposed device. It is shown that the difference did not raise new safety and effectiveness concerns.
Note 7	The uExcel DPR implemented on the uMI Panvivo EX and uMI Panvivo ES systems is algorithmically identical to the previously cleared uExcel DPR feature on the uMI Panvivo and uMI Panvivo S systems. The sole distinction lies in the declared intended use, uMI Panvivo ES and uMI Panvivo EX only support FDG (^{18}F-FDG) while uMI Panvivo and uMI Panvivo S supports several imaging agents. Performance and clinical image evaluation were conducted on the proposed device. It is shown that the difference did not raise new safety and effectiveness concerns.
Note 8	The Intelligent Assistant is a local auxiliary query tool that responds to PETCT operation-related questions based on validated knowledge (including user manuals and common issues). It does not control or modify the system's hardware, core software, scanning parameters, or reconstruction processes, nor does it alter the original operational workflow. The addition of this feature does 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.

- Performance tests for HYPER Iterative, AI EFOV, OncoFocus, NeuroFocus.Brain, uExcel DPR, Deep MAC, Digital gating and uKinetics.
- Sample clinical images for General, OncoFocus, NeuroFocus.Brain, uExcel DPR, HYPER Iterative and AI EFOV 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 from 20 human subjects. A total of 20 volunteers 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(%)**

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 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. In addition, DeepMAC 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 DeepMAC effectively corrects metal artifacts and improves tissue interpretability.

- ***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 EX and uMI Panvivo ES, comprising two NEMA IQ phantom datasets and a clinical dataset of eight human subjects. 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 7-12 minutes over 3-5 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

Subjects' Characteristics (N=8)	**N(%)**
Gender, N(%)	
Male	5 (62.5%)
Female	3 (37.5%)
Age, N(%)	
<30	2 (25.0%)
30-60	3 (37.5%)
>60	3 (37.5%)
Ethnicity, N(%)	
Asian	8 (100%)
Body Mass Index (BMI), N(%)	
Healthy weight (18.5-24.9)	4 (50.0%)
Overweight (25.0-29.9)	3 (37.5%)
Obesity (>=30.0)	1 (12.5%)

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 47% and an average SNR improvement of 131%;
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 (μ-map) synthesis network (CNN-AC) for more accurate attenuation correction and image registration.

We have conducted validation on the uMI Panvivo EX and uMI Panvivo ES system using clinical patient cases. A total of 13 volunteers with diverse demographic distributions covering various genders, age groups, and BMI groups (Table 6) were enrolled. The cases underwent PET/CT scans 80.23±19.44 min post-injection of 216.77±44.89 MBq FDG, with 2-3min per bed position.

Table 6 Distribution of volunteer dataset

Subjects' Characteristics (N=13)	**N(%)**
Gender, N(%)	
Male	7(54%)
Female	6(46%)
Age, N(%): Min=34, Max=90, Avg.=72.7, Std.=11.9	
30-44	1(8%)
45-64	1(8%)
>=65	11(85%)
Ethnicity, N(%)	
Asian	13(100%)
Body Mass Index (BMI), N(%): Min=20.4, Max=29.4, Avg.=23.5, Std.=2.9	
Healthy weight (18.5-24.9)	10(77%)
Overweight (25.0-29.9)	3(23%)

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

Evaluation Item	**Evaluation Method**	**Criteria**	**Results**
Volume relative to no respiratory motion correction (ΔVolume).	Calculating the OncoFocus 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 OncoFocus 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 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 μ-map estimation and image alignment. For non-FDG scans, the CT-based μ-map is used directly. Together, these approaches enable precise motion management, reduce blurring, and enhance diagnostic confidence in clinical brain PET/CT imaging.

  We have conducted validation on the uMI Panvivo ES and uMI Panvivo EX systems using one Monte Carlo-simulated brain phantom case and several clinical volunteer cases. For the Monte Carlo-simulated (MCS) case, we simulated one 500-second brain scan with the subject completely stationary, and another brain scan with identical simulation settings but with rotational motion around the neck occurring during the scan. For clinical volunteer cases, we retrospectively identified 7 cases with notable head motion artifacts in the conventional reconstruction protocols. The gender, age, ethnicity, and BMI group information for these 7 volunteers is summarized in Table 8. The cases underwent PET/CT scans 73.0±14.4 min post-injection of 243.9±55.5 MBq.

Table 8 Distribution of volunteer dataset

Subjects' Characteristics (N=7)	**N(%)**
Gender, N(%)	

Male	5(71.4%)
Female	2(28.6%)
Age, N(%): Min=24 Max=79, Avg.=57.4, Std.=21.7	
20-44	2(28.6%)
45-64	1(14.2%)
>=65	4(57.1%)
Ethnicity, N(%)	
Asian	7(100%)
Body Mass Index (BMI), N(%): Min=20.9, Max=28.3, Avg.=24.5, Std.=2.5	
Healthy weight (18.5-24.9)	4(57.1%)
Overweight (25.0-29.9)	3(42.9%)

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

Evaluation Item	Evaluation Method	Criteria	Results
Quantitative evaluation	Calculate ΔSUVmean in the high-uptake region for two MCS cases: one with motion introduced during simulation and reconstructed using NeuroFocus.Brain, and one stationary reconstructed without NeuroFocus.Brain.	The ΔSUVmean value is less than 10%.	Pass
	Calculate ΔSUVmean in the high-uptake region of the prefrontal cortex, relative to reconstruction without NeuroFocus.Brain for the same clinical scan with head motion.	The ΔSUVmean value is large than 0%.	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.

In addition, the comparison between reconstructed images with and without NeuroFocus.Brain were evaluated by two American Board of Radiologists-certified physicians. The evaluation reports from radiologists verified that NeuroFocus.Brain can reduce head motion artifacts and improve image quality, thereby enhancing diagnostic confidence compared with images reconstructed without NeuroFocus.Brain.

- ***AIEFOV***

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:
- AI 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 AIEFOV algorithm when scanned object exceed CT field of view.
- AI EFOV shall have consistent CT value, and PET image SUV by performing attenuation correction with CT generated with AIEFOV 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 6740 images of 4 patients (table 10) at different truncation situations were scanned in uMI Panvivo EX/ES to prove the effectiveness of AI EFOV. The clinical images were reviewed by two American Board qualified clinical experts for blind comparison regarding to image Artifacts, homogeneity of same tissue and diagnostic confidence in PET images.

Table 10 Distribution of volunteer dataset

Subjects' Characteristics (N=4)	N(%)
Gender, N(%)	
Male	2 (50.0%)
Female	2 (50.0%)
Age, N(%): Min=35 Max=73, Avg.=57.3, Std.=16.4	
20-44	1 (25.0%)
45-64	1 (25.0%)
>=65	2 (50.0%)
Ethnicity, N(%)	
Asian	4 (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)	4 (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 AIEFOV

Evaluation Item	Evaluation Method	Criteria	Results
Quantitative evaluation	For phantom study, the water phantom outside of CT scan-FOV was tested to compare the AIEFOV 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 AIEFOV algorithm will be compared.	Compared to the ground truth, the uniformity and SUV deviation of PET image obtained by using AIEFOV 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 AIEFOV or EFOV should result in consistent PET image SUV.	Pass

Bench tests showed that performing attenuation correction with CT images generated with AIEFOV 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 AIEFOV or EFOV results in consistent SUV. Clinical evaluation concluded AI 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.