August 30, 2024

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

Re: K241585
Trade/Device Name: uMI Panorama
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 1, 2024
Received: June 3, 2024

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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.

Submission Number *(if known)*

k241585

Device Name

uMI Panorama

Indications for Use *(Describe)*

The uMI Panorama is a diagnostic imaging system that combines two existing imaging modalities PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.
This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and treatment response evaluation for diseases, inflammation, infection and disorders in, but not limited to oncology, cardiology and neurology. The system maintains independent functionality of the CT device, allowing for single modality CT diagnostic imaging.
This 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.

510 (K) SUMMARY

K241585

1. **Date of Preparation**
June 1, 2024

2. **Sponsor Identification**

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

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3. **Identification of Proposed Device**

Device Name: uMI Panorama
Common Name: Positron Emission Tomography and Computed Tomography Systems
Model(s): uMI Panorama GS

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

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

Predicate Device

510(k) Number: K231572
Device Name: uMI Panorama
Model(s): uMI Panorama GS
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

Reference Device#1

510(k) Number: K193241

Device Name: uMI 550
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

Reference Device#2

510(k) Number: K232712
Device Name: uMI Panorama
Model(s): uMI Panorama 28, uMI Panorama 35
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

Reference Device#3

510(k) Number: K210001
Device Name: HYPER AiR
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS
Review Panel: Radiology

5. Device Description:

The proposed device uMI Panorama GS combines a 148 cm axial field of view (FOV) PET and multi-slice CT system to provide high quality functional and anatomical images, fast PET/CT imaging and better patient experience. The system includes PET gantry, CT gantry, patient table, power supply cabinet, console and reconstruction system, chiller, vital signal module.

The uMI Panorama GS has been previously cleared by FDA via K231572. The mainly modifications performed on the uMI Panorama GS (K231572) in this submission are due to the algorithm update of AIIR, the addition of HYPER Iterative, uExcel DPR, RMC, AIEFOV, Motion Management, CT-less AC, uKinetics, Retrospective Respiratory-gated Scan, uExcel Unity and uExcel iQC.
Details about the modifications are listed as below:

- AIIR, also named Deep IR, has been cleared via K223028 on uCT ALTLAS Astound (CT subsystem of the predicate device uMI Panorama GS). Deep IR can reduce image noise and streak artifacts, increase high contrast spatial resolution and improve low contrast detectability, and it can correspondingly reduce the dose required for diagnostic CT images. Compared with the previous clearance, AIIR in this submission changed its deep learning (DL) network from a

variational network to a three-dimension deep convolutional neural network (3D-DCNN).

- HYPER Iterative (cleared via K193241), 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.
- uExcel DPR (also named HYPER AiR, cleared via K210001) incorporates pre-trained neural networks in the iteration reconstruction process to reduce noise and improve contrast of fluorodeoxyglucose (FDG) PET images.
- RMC, Respiratory Motion Correct (also named uExcel Focus or OncoFocus, cleared via K232712) is an AI-based algorithm to reduce respiratory motion artifacts in PET/CT images and at the same time reduce the PET/CT misalignment.
- uKinetics (cleared via K232712) is a kinetic modeling toolkit for both indirect and direct parametric imaging. Compared the previous clearance, uKinetics for uMI Panorama GS only supports the indirect parametric imaging, in which the parametric images were generated from post-reconstruction voxel-based fitting of dynamic PET. The toolkit also supports PBIF template generation and scaling.
- AIEFOV is an extended field of view algorithm connecting projection data extrapolation and deep learning. AIEFOV is expected to be used to obtain improved image quality when scanning objects exceed the CT scan-FOV, such as bariatric patients or arms-down scan positioning.
- Motion Management (MM) is a unified solution for addressing the patient motion related artifacts due to head, torso and respiratory motion. It can execute motion management algorithms for different regions of interest (ROI) according to the user-selected commands, eliminating motion-induced blurring of PET images, removing the PET/CT misalignment introduced AC artifacts, addressing the PET/CT misalignment in the final image, as well as improving the accuracy of SUV.
- CT-less AC is developed with deep learning technology to achieve PET AC without CT images. The reconstructed PET AC images will be registered to a user-selected CT images to formulate well matched PET/CT fusion images which is used for the further analysis. Even the AC was performed without CT, there is no significant quantitative difference between the final PET image and AC with CT (CTAC).
- Retrospective Respiratory-gated Scan (cleared via K232712) utilizes respiratory signal to visualize the respiratory motion during scan. Data can be reconstructed with phase-based or amplitude-based binning.
- uExcel Unity (cleared via K232712) is a visual parameter calculation tool to achieve accurate SUV normalization with one click. It reduces the impact of differences in equipment performance, acquisition parameters, reconstruction parameters and other differences.
- uExcel iQC (cleared via K232712) is a novel radioactive free automatic QC solution for the PET system instead of utilizing the systems intrinsic radioactive properties.

6. Indications for Use

The uMI Panorama is a diagnostic imaging system that combines two existing imaging modalities PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.

This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and treatment response evaluation for diseases, inflammation, infection and disorders in, but not limited to oncology, cardiology and neurology. The system maintains independent functionality of the CT device, allowing for single modality CT diagnostic imaging.

This 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.

7. Comparison of Technological Characteristics with the Predicate Device

The uMI Panorama GS employs the same basic operating principles and fundamental technologies, and has the same indications for use as the predicate device uMI Panorama GS(K231572). A comparison between the technological characteristics of proposed and predicate and reference devices is provided as below.

ITEM	**Proposed Device** **uMI Panorama GS**	**Predicate Device** **uMI Panorama GS(K231572)**
Gantry	760 mm bore	760 mm bore
PET system	Scintillator material: LYSO Number of detector rings: 504 Axial FOV: 148 cm	Scintillator material: LYSO Number of detector rings: 504 Axial FOV: 148 cm
CT System	uCT ATLAS Astound	uCT ATLAS Astound
Maximum table load	250 kg	250 kg
Software function		

AIIR	Yes	Yes
HYPER Iterative	Yes	No
uExcel DPR	Yes	No
RMC	Yes	No
uKinetics	Yes	No
AIEFOV	Yes	No
Motion Management (MM)	Yes	No
CT-less AC	Yes	No
Retrospective Respiratory-gated Scan	Yes	No
uExcel Unity	Yes	No
uExcel iQC	Yes	No

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

8. Performance Data

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

Non-Clinical Testing

Non-clinical testing including Algorithm and Image performance tests were conducted 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/AAMIES60601-1: 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
- IEC60601-1-2: 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

Software

- NEMA PS 3.1-3.20(2022d): 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 evaluation report for AIIR, HYPER Iterative, uExcel DPR, RMC, AIEFOV, Motion Management, CT-less AC and uKinetics.
- Sample clinical images for AIIR, HYPER Iterative, uExcel DPR, RMC, AIEFOV, Motion Management and CT-less AC were reviewed by U.S. board-certified radiologists. It was shown that the proposed device can generate images as intended and the image quality is sufficient for diagnostic use.

Summary of functionality using deep learning algorithm

- AIEFOV

The training data contains 506476 images covered 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
- patients 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.

Besides the performance bench tests, a clinical evaluation was also performed. The clinical test dataset included 9303 images of 13 patients (table 1) at different truncation situations were scanned in uMI Panorama GS 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 1 Subject Information (N=13)

Characteristic	Value
Age (year)	62 ± 14 (35–79)*
Sex (male:female)	7:6
BMI (kg/m^2)	25.0 ± 3.5 (21.2–31.4)*
Injected activity (mCi/kg)	0.10 ± 0.01 (0.04–0.11)*

* Data were presented as mean ± SD (range).

The training dataset used for the training of AIEFOV algorithm was independent of the dataset used to test the algorithm.

Bench tests showed that performing attenuation correction with AIEFOV can improve the CT number and the accuracy of SUV, in cases where the scanned object exceeds the CT field of scan-FOV. Meanwhile, when the scanned object did not exceed the CT scan-FOV, either AIEFOV or EFOV results in consistent SUV and CT number. Clinical evaluation concluded the image quality of PET attenuated with AIEFOV provides sufficient diagnostic confidence.

Based on the bench tests and clinical evaluation, the performing attenuation correction with AIEFOV CT can improve the accuracy of image SUV, in cases where the scanned

object exceeds the CT field of view.

Summary

The items described in this premarket submission are supported with the results of the testing mentioned above, the uMI Panorama GS was found to have a safety and effectiveness profile that is similar to the predicate device.

9. 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.