October 3, 2023

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

Re: K232712
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: September 5, 2023
Received: September 5, 2023

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
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

k232712

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.

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UNITED IMAGING

510 (K) SUMMARY

1. **Date of Preparation**
   September 5, 2023

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 Panorama
   Common Name: Positron Emission Tomography and Computed Tomography Systems
   Model(s): uMI Panorama 28, uMI Panorama 35

   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: K223325
   Device Name: uMI Panorama
   Regulation Name: Emission Computed Tomography System
   Regulatory Class: II
   Product Code: KPS, JAK
   Review Panel: Radiology

   Reference Device

   510(k) Number: K173578
   Device Name: Biograph mCT and MCT Flow PET/CT Scanners

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

5. Device Description:

The proposed device uMI Panorama combines a 280 or 350 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 Panorama has been previously cleared by FDA via K223325. The mainly modifications performed on the uMI Panorama (K223325) in this submission are due to the algorithm update of uExcel Focus (also named OncoFocus) and the addition of uKinetics. This time, uExcel Focus adds deep learning technology based on the original technology and could be performed as intended. uKinetics is a new function, which is used to generate both indirect and direct parametric images.

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

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

ITEM	**Proposed Device** **uMI Panorama**	**Predicate Device** **uMI Panorama (K223325)**
Patient bore size	760mm	760mm
PET System	Scintillator material: LYSO Number of detector rings: • 96 (uMI Panorama 28) • 120 (uMI Panorama 35) Axial FOV: • 280mm (uMI Panorama 28) • 350mm (uMI Panorama 35)	Scintillator material: LYSO Number of detector rings: • 96 (uMI Panorama 28) • 120 (uMI Panorama 35) Axial FOV: • 280mm (uMI Panorama 28) 350mm (uMI Panorama 35)
CT System	uCT ATLAS Astound (K223028)	uCT ATLAS Astound (K223028)
Maximum table load	318kg	318kg
Advanced Feature		
uExcel Focus	Yes	Yes
uKinetics	Yes	No

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

8. Performance Data

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

Non-Clinical Testing

Non-clinical testing including dosimetry and image performance tests were conducted for the uMI Panorama 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 XR 25-2019, Computed Tomography Dose Check
- NEMA XR 28-2018, Supplemental Requirements For User Information And System Function Related To Dose In CT
- NEMA XR 29-2013, Standard Attributes on CT Equipment Related to Dose Optimization and Management
- IEC 61223-3-5 2004 Edition 1.0, Evaluation And Routine Testing In Medical Imaging Departments - Part 3-5: Acceptance Tests - Imaging Performance Of Computed Tomography X-ray Equipment [Including: Technical Corrigendum 1 (2006)]
- NEMA NU 2-2018, Performance Measurements of Positron Emission Tomographs

Software

- NEMA PS 3.1-3.20(2016): 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 10993-5: 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
- Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography

Performance Verification

Engineering bench testing was performed on uMI Panorama with uExcel Focus and uMI Panorama with uKinetics to support substantial equivalence and the product performance claims.

uExcel Focus
The images were compared for:

- Volume relative to no motion correction (ΔVolume)
- Maximum standardized uptake value relative to no motion correction (ΔSUVmax)
- Mean standardized uptake value relative to no motion correction (ΔSUVmean).

The performance evaluation showed that uExcel Focus could reduce respiratory motion effects and improve the accuracy of SUV and lesion volume in comparison with no motion correction.

uKinetics
The images were compared for:

- Bias of area under curve (AUC) of the estimated image-derived input function (IDIF).
- Bias of Ki and intercept in the hot spheres in the IQ phantom.
- Coefficient of variation (CoV) of the background region in the IQ phantom.

Bench test showed that uKinetics can provide quantitatively accurate parametric images.

Clinical Image Evaluation

A blind comparison was conducted between uMI Panorama with/without uExcel Focus. Two American board-certified nuclear medicine physicians were invited to evaluate the images independently. Clinical evaluation shows that all images produced by uMI Panorama with uExcel Focus are sufficient for clinical diagnosis and uExcel Focus can reduce attenuation correction artifacts and improve PET-CT alignment.

Summary

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