



December 12, 2024

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

Re: K243538

Trade/Device Name: uMI Panvivo (uMI Panvivo); uMI Panvivo (uMI Panvivo S)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: November 13, 2024
Received: November 15, 2024

Dear Gao Xin:

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.

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,

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

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

Submission Number (if known)

k243538

Device Name

uMI Panvivo (uMI Panvivo);
uMI Panvivo (uMI Panvivo S)

Indications for Use (Describe)

The uMI Panvivo 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 uMI Panvivo system generates images depicting the distribution of these radiopharmaceuticals. The images produced by the uMI Panvivo 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, infection and inflammation, neurology. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (K) SUMMARY

K243538

1. Date of Preparation

November 13, 2024

2. Sponsor Identification

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Contact Person: Xin GAO

Position: Regulatory Affair Manager

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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

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: K241596

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 235/295 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 was previously cleared by the FDA via K241596. The modification in this submission involves the addition of a new model. The previous uMI Panvivo(K241596) is designed with scalable PET rings and uMI Panvivo S is scaling to 80 PET rings compare to the uMI Panvivo 100 PET rings.

6. Intended Use

The uMI Panvivo 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, 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 uMI Panvivo 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 uMI Panvivo system generates images depicting the distribution of these radiopharmaceuticals. The images produced by the uMI Panvivo 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, infection and inflammation, neurology. 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 uMI Panvivo 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 Panvivo		Predicate Device uMI Panvivo (K241596)
Model	uMI Panvivo S	uMI Panvivo	uMI Panvivo
Patient bore size	700mm	700mm	700mm
PET System	Scintillator material: LYSO Number of detector rings: • 80 Axial FOV: • 235mm	Scintillator material: LYSO Number of detector rings: • 100 Axial FOV: • 295 mm	Scintillator material: LYSO Number of detector rings: • 100 Axial FOV: • 295 mm
CT System	uCT 780	uCT 780	uCT 780
Maximum table load	250kg	250kg	250kg

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

9. Performance Data

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

Non-Clinical Testing

Non-clinical testing 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(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 10993-1:2018, 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.

- Sample clinical images were reviewed by U.S. board-certified radiologist. It was shown that the proposed device can generate images as intended and the image quality is sufficient for diagnostic use.

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.