January 27, 2025

RAYSOLUTION Healthcare Co., Ltd
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K241266
Trade/Device Name: Imaging system of positron emission and X-ray computed tomography (DigitMI 930)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: May 6, 2024
Received: May 6, 2024

Dear Ray Wang:

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,

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)*

k241266

Device Name

Imaging system of positron emission and X-ray computed tomography (DigitMI 930)

Indications for Use *(Describe)*

The Imaging system of positron emission and X-ray computed tomography is a PET/CT system for producing attenuation corrected PET images. It is intended to be used by qualified health care professionals for imaging the distribution and localization of any positron-emitting radiopharmaceutical in a patient, for the assessment of metabolic (molecular) and physiologic function in patients, with a wide range of sizes and extent of disease, of all ages.
Imaging system of positron emission and X-ray computed tomography is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The images produced by the system may be used by physicians to aid in radiotherapy treatment planning, therapy guidance and monitoring, and in interventional radiology procedures. The images may also be used for precise functional and anatomical mapping (localization, registration, and fusion).
When used with radiopharmaceuticals approved by the regulatory authority in the country of use, the raw and image data is an aid in; detection, localization, evaluation, diagnosis, staging, restaging, monitoring, and/or follow up, of abnormalities, lesions, tumors, inflammation, infection, organ function, disorders, and/or disease, such as, but not limited to, those in oncology, cardiology, and neurology. Examples of which are:
Cardiology:
· Cardiovascular disease
· Myocardial perfusion
· Myocardial viability
· Cardiac inflammation
· Coronary artery disease
Neurology:
· Epilepsy
· Dementia, such as Alzheimer's disease, Lewy body dementia, Parkinson's disease with dementia, and frontotemporal dementia.
· Movement disorders, such as Parkinson's and Huntington's disease
· Tumors
· Inflammation
· Cerebrovascular disease such as acute stroke, chronic and acute ischemia
· Traumatic Brain Injury (TBI)
Oncology/Cancer:
· Non-Small Cell Lung Cancer
· Small Cell Lung Cancer
· Breast Cancer
· Prostate Cancer
· Hodgkin disease
· Non-Hodgkin lymphoma
· Colorectal Cancer
· Melanoma

Imaging system of positron emission and X-ray computed tomography is also intended for stand-alone, diagnostic CT imaging in accordance with the stand-alone CT system's cleared indications for use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: k241266

1. Date of Preparation: 05/06/2024

2. Sponsor

RAYSOLUTION Healthcare Co., Ltd
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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Imaging system of positron emission and X-ray computed tomography
Common Name: System, Tomography, Computed, Emission; System, X-Ray, Tomography, Computed
Model(s): DigitMI 930
Regulatory Information:

Classification Name: System, Tomography, Computed, Emission; System, X-Ray, Tomography, Computed
Classification: II
Product Code: KPS; JAK
Regulation Number: 21 CFR 892.1200; 21 CFR 892.1750
Regulation Name: Emission computed tomography system
Review Panel: Radiology

Intended Use:

The PET/CT system is intended for CT attenuation corrected, anatomically localized PET imaging of the distribution of positron-emitting radiopharmaceuticals. It is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The system is also intended for stand-alone, diagnostic CT imaging.

Indication For Use Statement:

The DigitMI 930 is a PET/CT system for producing attenuation corrected PET images. It is intended to be used by qualified health care professionals for imaging the distribution and localization of any positron-emitting radiopharmaceutical in a patient, for the assessment of metabolic (molecular) and physiologic function in patients, with a wide range of sizes and extent of disease, of all ages.

The DigitMI 930 is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs.The images may also be used for precise functional and anatomical mapping (localization,registration,and fusion).

When used with radiopharmaceuticals approved by the regulatory authority in the country of use, the raw and image data is an aid in; detection, localization, evaluation, diagnosis,staging, restaging, monitoring, and/or follow up, of abnormalities, lesions, tumors,inflammation, infection, organ function, disorders, and/or disease, such as, but not limited to, those in oncology, cardiology, and neurology. Examples of which are:

Cardiology:

- Cardiovascular disease
- Myocardial perfusion
- Myocardial viability
- Cardiac inflammation
- Coronary artery disease

Neurology:

- Epilepsy
- Dementia, such as Alzheimer's disease, Lewy body dementia, Parkinson's disease with dementia, and frontotemporal dementia.
- Movement disorders, such as Parkinson's and Huntington's disease
- Tumors

- Inflammation
- Cerebrovascular disease such as acute stroke, chronic and acute ischemia
- Traumatic Brain Injury (TBI)

Oncology/Cancer:

- Non-Small Cell Lung Cancer
- Small Cell Lung Cancer
- Breast Cancer
- Prostate Cancer
- Hodgkin disease
- Non-Hodgkin lymphoma
- Colorectal Cancer
- Melanoma

The DigitMI 930 is also intended for stand-alone, diagnostic CT imaging in accordance with the stand-alone CT system's cleared indications for use.

5. Device Description

The Imaging system of positron emission and X-ray computed tomography (model: DigitMI 930) is a PET/CT diagnostic imaging system combining a Positron Emission Tomography (PET) System and a Computed Tomography (CT) System.
The Imaging system of positron emission and X-ray computed tomography (model: DigitMI 930) consists of a scanning system, power distribution unit, table system, data processing system, and console system. The PET part consists of a 72 ring LYSO detector, while the CT part has 64 physical rows of detectors.

6. Predicate Device Identification

Predicate Device:
510(k) Number: K161574
Product Name: Discovery MI
Manufacturer: GE Medical Systems, L.L.C.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 2020 Medical electrical equipment - Part 1: General requirements for basic

safety and essential performance

- IEC 60601-1-3: 2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 10993-5: 2009 Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- NEMA NU 2-2018 Performance Measurements of Positron Emission Tomographs
- 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
- IEC 60601-2-28:2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-44: 2016 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
- IEC 61223-2-6:2006 Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment
- IEC 61223-3-5:2019 Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment
- NEMA PS3.1-3.20 2022d Digital Imaging and Communications in Medicine (DICOM) Set
- ISO 60825-1:2014 Safety of laser products - Part 1: Equipment classification, and requirements
- ISO 14971: 2019 Medical devices - Application of risk management to medical devices

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device (K161574) Discovery MI	Remark
Product Code	KPS; JAK	KPS; JAK	SAME
Regulation No.	21 CFR 892.1200; 21 CFR 892.1750	21 CFR 892.1200; 21 CFR 892.1750	SAME

Class	2	2	SAME
Type of Use	Prescription Use	Prescription Use	SAME
Intended Use	The PET/CT system is intended for CT attenuation corrected, anatomically localized PET imaging of the distribution of positron-emitting radiopharmaceuticals. It is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The system is also intended for stand-alone, diagnostic CT imaging.	The Discovery MI PET/CT system is intended for CT attenuation corrected, anatomically localized PET imaging of the distribution of positron-emitting radiopharmaceuticals. It is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The system is also intended for stand-alone, diagnostic CT imaging.	SAME

Table 2 Performance Comparison

ITEM	**Proposed Device**	**Predicate Device (K161574) Discovery MI**	Remark
PET Specification:			
Sensitivity	> 16.3cps/kBq	≥ 12.6cps/kBq	Analyse 1
NECR Peak Value	> 125kcps@5.3kBq/cc; > 325kcps@33.9kBq/cc	≥ 162 kcps@18kBq/cc	Analyse 1
Peak True Count Rate	> 1284kcps@49.2kBq/cc	≥ 847.1 kcps@34.2kBq/cc	Analyse 1
PET Scatter Fraction	≤ 39%	≤ 45%	Analyse 1
Count Rate Bias	≤ ±5%	≤ ±5.5%	Analyse 1
Axial FWHM@1cm	< 3.7mm	< 4.84mm	Analyse 1
Transaxail FWHM@1cm	< 3.9mm	< 6.0mm	Analyse 1
Axial FWHM@10cm	<4.0mm	< 5.61mm	Analyse 1
Transaxial FWHM@10cm	< 4.0mm	< 7.56mm	Analyse 1
CT Specification:			
Scan Regime	Continuous Rotation	Continuous Rotation	Analyse 1
Scan Modes	Topo Axial Scan Helical Scan	Topo Axial Scan Helical Scan	Analyse 1
Z-plane coverage	40mm	40mm	Analyse 1
Number of detector row	64	64	Analyse 1
Minimum slice thickness	0.6	0.6	Analyse 1
Rotation speed	0.42 s/360°	Up to 0.35 sec for 360° rotation	Analyse 1
Table Maximum table load	204kg	227kg	Analyse 1
Safety:			
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Analyse 2

Electrical Safety	IEC 60601-1	IEC 60601-1	SAME
EMC	IEC 60601-1-2	IEC 60601-1-2	SAME

Analyse 1:

The device and predicate device have difference in performance specification, such as Sensitivity NECR Peak Value, Peak True Count Rate, PET Scatter Fraction, Count Rate Bias, Axial FWHM@1cm, Transaxail FWHM@1cm, Axial FWHM@10cm, Transaxial FWHM@10cm Scan Regime, Scan Modes, Z-plane coverage, Number of detector row, Minimum slice thickness, otation speed and Table Maximum table load. But the proposed device have tested for measurement accuracy by performance testing and software validation, so these difference can prove the effectiveness of propose device.

The proposed device has tested according with the safety standard IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-3 for the safety. The proposed device has tested according with the performance standard NEMA NU 2, NEMA XR 25, NEMA XR 28, IEC 60601-2-28, IEC 60601-2-44, IEC 61223-2-6 and IEC 61223-3-5 for the effectiveness. The proposed device has tested according with the ISO 10993-5, ISO 10993-10 and ISO 10993-23 for the Biocompatibility.

Therefore, the differences above between the proposed device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety. No new technology is applied in the subject device. Most of the main aspects on effectiveness and safety between the proposed device and predicate device are same. The differences are slight so that no substantial influence on the effectiveness and safety.

Analyse 2:

The proposed device is different in Biocompatibility Testing Standard from the predicate device. The proposed device was tested according to ISO 10993-1. We tested ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021, which are FDA recognized standard. The results of the biocompatibility test report show that the proposed device meets the biocompatibility requirements. Therefore, this difference will not affect the safety in Biocompatibility of the proposed device.

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and is substantially equivalent to the predicate device and performs as well as or better than the predicate device (K161574).