November 25, 2025

Trustees of the University of Pennsylvania
Joel Karp
Section Chief, Physics & Instrumentation Group
5th Floor, Franklin Building
3451 Walnut Street
Philadelphia, Pennsylvania 19104-6205

Re: K251401
Trade/Device Name: PennPET Explorer Positron Emission Tomograph
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: October 10, 2025
Received: October 10, 2025

Dear Joel Karp:

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.

510(k) Number *(if known)*
K251401

Device Name
PennPET Explorer Positron Emission Tomograph

Indications for Use *(Describe)*
The PennPET Explorer PET system is a diagnostic imaging device that, together with the co-located IQon CT scanner, combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The IQon CT system images anatomical cross-sections by computer reconstruction of X-ray transmission data. The PET system images the distribution of PET anatomy-specific radiopharmaceuticals in the patient. Together, these systems are used for the purposes of detecting, localizing, diagnosing, staging, re-staging, and follow-up for monitoring therapy response of various diseases in oncology, cardiology, and neurology.

The system is intended to image the whole body, heart, brain, lung, gastrointestinal, bone, lymphatic, and other major organs for a wide range of patient types, sizes, and extent of diseases. The CT scanner can also be operated as fully functional, independent diagnostic tool, including for use in radiation therapy planning.

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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1. 510(k) Summary in accordance with 21 CFR 807.92

K251401

Date:	2025-10-24
Submitter:	Trustees of the University of Pennsylvania 5th Floor, Franklin Building 3451 Walnut Street Philadelphia, PA 19104-6205
Primary Contact Person:	Joel S. Karp, PhD Section Chief, Physics & Instrumentation Group Department of Radiology University of Pennsylvania Tel: +1 215-573-4998 E-mail: joelkarp@pennmedicine.upenn.edu
Device Trade Name:	PennPET Explorer Positron Emission Tomograph
Common Name:	Positron Emission Tomography (PET) System Computed Tomography (CT) System
Classification Panel:	Radiology
Classification Names:	Emission Computed Tomography System, 21 CFR 892.1200 X-ray Computed Tomography, 21 CFR 892.1750
Primary Product Code:	KPS
Secondary Product Code:	JAK
Device Class:	Class II
Predicate Device:	K123599, Ingenuity TF Digital (Vereos) PET/CT System
Reference Devices:	K172406, Ingenuity TF PET/CT System K081135, Ingenuity TF Big Bore (Gemini TF Big Bore) PET/CT System
Device Description:	The PennPET Explorer is based on the PET technology of its predicate device, the Philips Vereos PET/CT scanner, but follows the model of its reference device, the previous Philips Gemini TF PET/CT by having co-located—yet separated—PET and CT scanners served by a common patient table. The PennPET Explorer uses a newly designed 142 cm axial field-of-view (AFOV) PET gantry and is intended to be used with a co-located Philips IQon multi-energy CT and patient table. The PennPET Explorer PET gantry is a modular system comprising six PET detector rings stacked axially, yielding a 142 cm axial FOV. This allows imaging of the human head, torso, and upper legs in a single frame without moving the patient. The entire imaging chain of components from the detectors to the data acquisition computers is supplied by Philips and consists of components that are used in the

	Vereos PET scanner. The mechanical structure and data processing software have been modified and developed to handle the additional data from all six PET rings simultaneously. Each of the six detector rings is substantially equivalent to a Philips Vereos PET scanner.
Indications for Use / Intended Use:	The PennPET Explorer PET system is a diagnostic imaging device that, together with the co-located IQon CT scanner, combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The IQon CT system images anatomical cross-sections by computer reconstruction of X-ray transmission data. The PET system images the distribution of PET anatomy-specific radiopharmaceuticals in the patient. Together, these systems are used for the purposes of detecting, localizing, diagnosing, staging, re-staging, and follow-up for monitoring therapy response of various diseases in oncology, cardiology, and neurology. The system is intended to image the whole body, heart, brain, lung, gastrointestinal, bone, lymphatic, and other major organs for a wide range of patient types, sizes, and extent of diseases. The CT scanner can also be operated as fully functional, independent diagnostic tool, including for use in radiation therapy planning.
Comparison of Indications for Use:	There are two differences between the indications for use for the Philips Vereos (predicate device) and the PennPET Explorer: 1. The Philips Vereos combines the PET and CT into a single unit, while the PennPET Explorer is a standalone PET Imaging system that uses CT data and patient positioning provided by a collocated but electrically and mechanically independent Philips IQon CT scanner. This two-unit configuration is functionally equivalent to the single-unit Vereos. 2. The Philips Vereos' Indications for Use states that "Both subsystems can also be operated as fully functional independent diagnostic tools." Currently accepted clinical practice requires CT-based measured attenuation correction for any PET scan, so the PennPET Explorer Indications for Use do not include PET-only operation.
Technology:	The PennPET Explorer employs the same fundamental technology as the currently marketed and predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599). The PennPET Explorer modifies the currently marketed and predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599) by extending the axial field-of-view (AFOV) from 16.4 cm to 142 cm. This is accomplished by combining six Vereos detector rings stacked axially into a single gantry. Other changes to support the multi-ring configuration include i) modified sensor board firmware to allow

	readout of all detector elements and data collection over the full 142-cm axial range, ii) modified cooling to enable a multi-ring configuration with minimal gaps between rings and to allow for operation at a lower temperature, leading to improved time-of-flight resolution, iii) modified couch to enable the full travel for PET/CT imaging, iv) modified software to support data processing of the larger, multi-ring data sets. All system components are identical to the marketed predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599) and have the same functionality as the currently marketed and predicate device (K123599). The extension of the AFOV by combining six Vereos rings leads to a sensitivity gain for measuring coincidence events, but otherwise performs in a substantially equivalent manner as the single-ring Vereos. The extension of the AFOV in the PennPET Explorer and related modifications do not impact safety and effectiveness of the PET/CT system.
Summary of Non-Clinical Performance Data:	Non-clinical performance testing has been performed on the PennPET Explorer and demonstrates compliance with the following International and FDA recognized consensus standards and FDA guidance document(s). Design Verification activities demonstrate that the PennPET Explorer meets the established design input requirements. Design Verification also included image quality verification and risk analysis risk mitigation testing. The following tests were performed on the PennPET Explorer according to the following international standards and FDA recognized consensus standards and FDA guidance documents: • NEMA NU 2-2018, 12-326, Performance Measurements of Positron Emission Tomographs • IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION 19-36 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests • AIM Standard 7321731 Rev. 3.00 2021-06-04 19-45 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard • IEC TR 60601-4-2 Edition 1.0 2016-05 19-19 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

	• IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION 19-49 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons.Text) [Incl. AMD2:2021] The following tests were performed on the marketed predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599) according to the following international standards and FDA recognized consensus standards and FDA guidance documents: • IEC 60601-1:1988/A1:1991/A2:1995, Medical electrical equipment -- Part 1: General requirements for safety. Including applicable US and international deviations. • IEC 60601-1-1:2000, Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems • IEC 60601-1-2:2001/A1:2004 , Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests • IEC 60601-1-3:1994, Medical electrical equipment -- Part 1: General requirements for safety -- 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment • IEC 60601-1-4:1996/A1:1999, Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems • IEC 60601-2-32:1994, Medical electrical equipment -- Part 2: Particular requirements for the safety of associated equipment of X-ray equipment • IEC 60601-2-44:2001/A1:2002, Medical electrical equipment -- Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography • NEMA NU2-2007, Measurements of Positron Emission Tomographs Device-Specific Guidance Documents: • Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems, December 3, 1998 • Guidance for Industry and FDA Administration Staff - Content of Premarket Submissions for Device Software Functions, June 14, 2023

	• Guidance for Industry and FDA Administration Staff - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, June 27, 2025 • Guidance for Industry and FDA Administration Staff - Electromagnetic Compatibility (EMC) of Medical Devices, June 6, 2022 Non-clinical design validation testing demonstrates that the PennPET Explorer can be used as defined in its clinical workflow and intended use. This testing includes internal PET AR image evaluation as well as External clinical images reviewed by certified board radiologists. All the testing described above were used to support the substantial equivalence of the PennPET Explorer with extended AFOV and revised software and demonstrate that the PennPET Explorer with extended AFOV and revised software application: • Complies with the aforementioned international and FDA-recognized consensus standards and/or FDA device specific guidance document, and; • Meets the acceptance criteria and is adequate for its intended use. Therefore, the PennPET Explorer is substantially equivalent to the currently marketed and predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599) in terms of safety and effectiveness.
Summary of Clinical Performance Data:	The PennPET Explorer did not require any clinical study. The clinical evaluation was conducted via simulated use testing and is accounted in the summary of "Non-Clinical Testing" section of the summary. The substantial equivalence to the currently marketed and predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599) was demonstrated with the following attributes: • Design Features • Indication for use • Technological characteristics • Safety and effectiveness Sample clinical images were reviewed and evaluated by certified radiologists. All images were evaluated to be as good or better than the predicate device due to its superior sensitivity.
Substantial Equivalence Conclusion:	The PennPET Explorer is substantially equivalent to the currently marketed and predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599), in terms of design features, indications for use, fundamental scientific technology and safety and effectiveness, with the advantages of improved time-of-flight resolution and improved sensitivity for detecting coincidence events due to the longer AFOV.

	The extension of the AFOV for the PennPET Explorer does not introduce any new risks nor impact the safety and effectiveness of the PennPET Explorer. Additionally, substantial equivalence was demonstrated by non-clinical (verification and validation) performance tests provided in this 510(k) premarket notification. These tests demonstrate that the PennPET Explorer complies with the design input requirements and the international and FDA-recognized consensus standards and that it is as safe and effective as the currently marketed and predicate device, Ingenuity TF Digital (Vereos) PET/CT (K123599) without raising any new safety and/or effectiveness concerns.