Philips Medical Systems Nederland B.V.
% Carmit Shmuel
Regulatory Affairs Specialist
Veenpluis 6
Best, 5684 PC
NETHERLANDS

August 6, 2021

Re: K211764
Trade/Device Name: Vereos PET/CT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 3, 2021
Received: June 8, 2021

Dear Carmit Shmuel:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211764

Device Name
Vereos PET/CT

Indications for Use *(Describe)*
The Vereos PET/CT System is a diagnostic imaging device that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem images anatomical cross-sections by computer reconstruction of x-ray transmission data. The PET subsystem images the distribution of PET anatomy-specific radiopharmaceuticals in the patient. The Philips Vereos PET/CT system is used for the purpose 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. Both subsystems can also be operated as fully functional, independent diagnostic tools including application of the CT scanner for diagnosis and 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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SECTION 5 510(K) SUMMARY

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: June 3, 2021

Manufacturer:
Philips Medical Systems Nederland B.V.
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5684 PC BEST
The Netherlands
Establishment Registration Number: 3015777306

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Director of Regulatory Affairs
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Device*:*

Trade Name:	Vereos PET/CT
Common name:	Positron Emission Computed Tomography, Computed Tomography X-Ray
Classification Name:	Emission Computed Tomography Systems, X-Ray Computed Tomography
Classification Regulation:	21 CFR 892.1200 21 CFR 892.1750
Classification Panel:	Radiology
Device Class:	II
Primary Product Code:	KPS
Secondary Product Code:	JAK

Predicate Device:

Trade Name:	Vereos PET/CT
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K210880 (Predicate)
Classification Name:	Emission Computed Tomography Systems, X-Ray Computed Tomography
Classification Regulation:	21 CFR 892.1200 21 CFR 892.1750
Classification Panel:	Radiology
Device Class:	Class II
Product Code: Secondary Product Code:	KPS JAK

Reference Device:

Trade Name:	Discovery PET/CT 710 Clarity Edition
Manufacturer:	GE Medical Systems LLC
510(k) Clearance:	K133657
Classification Name:	Emission Computed Tomography Systems, X-Ray Computed Tomography
Classification Regulation:	21 CFR 892.1200
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	KPS

Device Description:

The proposed Vereos PET/CT system is an integrated diagnostic X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) system designed for a wide range of diagnostic applications. Computerized Tomography (CT) is a medical imaging technique that uses X-rays to obtain cross sectional images of the head or body. The quality of the images depends on the level and amount of X-ray energy delivered to the tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. When interpreted by a trained physician, CT images provide useful diagnostic information. Positron Emission Tomography (PET) uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional images of biochemical and metabolic processes of organs within the body.

The proposed Vereos PET/CT system utilizes the CT technology to obtain anatomic images of the human body and PET technology to obtain functional images of the human body. The clinical value of both technologies increases with the capability to fuse the CT and PET images using Philips fusion viewer Image Fusion software to create a composite image for therapeutic planning. The system also provides tools for quantifying results from the CT and PET images and provides the means for a simplified review of the CT, PET, and fused images. The integration of the anatomical data from CT with the metabolic data from PET gives clinicians the visual information necessary to define the severity, as well as the extent, of the disease.

The system is comprised of the following system components/subsystems: positron emission tomography (PET); X-ray computed tomography (CT); a patient table; Operating station; Reconstruction Servers. On the gantry, the main active components are the x-ray high voltage (HV) power supply, the x-ray tube, and the detection system. These components of the proposed Vereos PET/CT are identical to the currently marketed and predicate device, Vereos PET/CT (K210880) with respect to technological specifications.

The proposed Vereos PET/CT System includes a modification to the currently marketed and predicate device, Vereos PET/CT (K210880). The modification is limited to the addition of an optional Adaptive reconstruction algorithm (“PET AR”) to be used as an additional reconstruction method for offline reconstructions. The interface of the PET AR with the Vereos system is additional protocols available to the user in the PET recon tool. In addition, a Software patch was released which limits the use of the PET AR reconstruction protocols for the scan type it’s compatible with and enables identifying the PET AR reconstructed images with visual identifier to differentiate them from regular PET results.

Indications for Use / Intended Use:

Vereos PET/CT system is a diagnostic imaging device that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem images anatomical cross-sections by computer reconstruction of x-ray transmission data. The PET subsystem images the distribution of PET anatomy-specific radiopharmaceuticals in the patient. The PET/CT system is used for the purpose 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. Both subsystems can also be operated as fully functional, independent diagnostic tools including application of the CT scanner for diagnosis and for use in radiation therapy planning.

The indication for use/intended use for the proposed Vereos PET/CT is identical to the currently marketed and predicate device, Vereos PET/CT (K210880) with respect to technological specifications.

Technological Characteristics

The Vereos PET/CT system with the PET AR algorithm employs the same fundamental technology as the currently marketed and predicate device, Vereos PET/CT (K210880).

The proposed Vereos PET/CT is a modification to the currently marketed and predicate device, Vereos PET/CT (K210880) that introduces a new optional Adaptive reconstruction algorithm called PET Adaptive Reconstruction (AR). This method iteratively reconstructs PET images to full convergence (Regularized Reconstruction). All other system components are identical to the currently marketed and predicate device, Vereos PET/CT (K210880) and have the same functionality and performance. Hence, the device description hasn't changed from the currently marketed and predicate device (K210880), other than the addition of the PET AR algorithm.

This 510(k) submission addresses the addition of a new optional Adaptive reconstruction software application being implemented in the currently marketed and predicate device, Vereos PET/CT system (K210880). The PET AR is an Artificial Intelligence-powered reconstruction algorithm that provides low noise and improves low contrast detectability as compared to OSEM (Ordered Subsets Expectation Maximization).

PET AR modification of the proposed Vereos PET/CT System does not impact safety and effectiveness.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed Vereos PET/CT system and demonstrates compliance with the following International and FDA recognized consensus standards and FDA guidance document(s). Design Verification activities demonstrate that the proposed Vereos PET/CT 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 currently marketed and predicate device, Vereos PET/CT (K210880) according to the following international standards and FDA recognized consensus standards and FDA guidance documents;

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1: 2012: Medical electrical equipment - Part 1: General requirements for safety

and essential performance (FDA Recognition Number: 19-4) (Including US Differences: ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012)

- IEC 60601-1-2:2014: Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (FDA Recognition Number: 19-8)
- IEC 60601-1-3:2008+A1:2013: Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (FDA Recognition Number: 12-269)
- IEC 60601-1-6:2010 +A1: 2013: Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability (FDA Recognition Number: 5-89)
- 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 (FDA Recognition Number: 12-309)
- IEC 60601-2-44:2009/AMD1:2012 and AMD2:2016: Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (FDA Recognition Number: 12-302)
- IEC 60825-1:2014: Safety of laser products - Part 1: Equipment classification, and requirements (FDA Recognition Number 12-273 and FDA laser notice No. 56 on IEC 60825-1 Ed. 3 issued on May 8, 2019).
- IEC 62366-1:2015: Medical devices — Part 1: Application of usability engineering to medical devices (FDA Recognition Number: 5-114)
- IEC 62304:2006 + A1: 2015: Medical device software - Software life-cycle processes (FDA Recognition Number: 13-79)
- ISO 10993-1:2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (FDA Recognition Number: 2-258)
- ISO 14971:2007 Medical devices – Application of risk management to medical devices (FDA Recognition Number: 5-40)

The software modification introduced in this application complies with IEC 62304:2006+A1;2015- see Section 17_002_D000812275- PET AR IEC 62304-1 Test Report.

There are no hardware changes from the currently marketed and predicate device, Vereos PET/CT (K210880), therefore, system-level testing done earlier are still applicable.

Device-Specific Guidance Document:

- Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems (issued December 3, 1998)
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014).

The traceability between the requirements, the hazard mitigations and the test protocols are described in the Traceability Matrix. The Traceability Matrix also shows the overall test results per requirement and hazard mitigation.

The results of the functional and non-functional regression tests as well as the user interface verification are provided in the Traceability Matrix. The detailed results are provided in the Full System Verification Test Report.

Non-clinical design validation testing demonstrates that the proposed Vereos PET/CT system 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 proposed Vereos PET/CT with PET Adaptive Reconstruction software application and demonstrate that the proposed Vereos PET/CT with PET Adaptive Reconstruction 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 proposed Vereos PET/CT is substantially equivalent to the currently marketed and predicate device, Vereos PET/CT (K210880) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The proposed Vereos PET/CT system 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, Vereos PET/CT (K210880) was demonstrated with the following attributes:

- Design Features
- Indication for use
- Technological characteristics
- Safety and effectiveness

Sample clinical images were provided with this submission, which were reviewed and evaluated by certified radiologists. All images were evaluated to have a good image quality.

Substantial Equivalence Conclusion:

The proposed Vereos PET/CT System with PET AR software application is substantially equivalent to the currently marketed and predicate device, Vereos PET/CT (K210880), in terms of design features, indications for use, fundamental scientific technology and safety and effectiveness.

The PET Adaptive Reconstruction software application for the proposed Vereos PET/CT System does not introduce any new risks nor impact the safety and effectiveness of the proposed Vereos PET/CT System.

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 proposed Vereos PET/CT system 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, Vereos PET/CT (K210880) without raising any new safety and/or effectiveness concerns.