Philips Medical Systems Nederland B.V.
℅ Nimit Shah
Regulatory Specialist
Veenpluis 4-6
Best, 5684 PC
NETHERLANDS

May 19, 2021

Re: K210880
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: March 23, 2021
Received: March 24, 2021

Dear Nimit Shah:

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)*
K210880

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

K210880

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

Date Prepared: March 23, 2021

Manufacturer:
Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC BEST
The Netherlands
Establishment Registration Number: 3015777306

Primary Contact Person:
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Device*:*

Trade Name:	Vereos PET/CT
Common name:	Position 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:	K123599 (cleared under Ingenuity TF Digital PET/CT)
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

Device Description:

The proposed Vereos PET/CT systems 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 the 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 Ingenuity TF Digital PET/CT (K123599) with respect to technological specifications.

Note: The name of the predicate device in its 510(k) was Ingenuity TF Digital PET/CT. After the 510(k) Clearance and prior to commercialization the name was changed to Vereos PET/CT. For clarity, the predicate device will be identified as Ingenuity TF Digital PET/CT throughout this 510(k) submission.

Indications for Use / Intended Use:

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.

The indication for use/intended use for the proposed Vereos PET/CT is identical to to the currently marketed and predicate device Ingenuity TF Digital PET/CT (K123599) with respect to technological specifications.

Technological Characteristics

The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the proposed Vereos PET/CT System have the same

fundamental design characteristics and are based on the same technologies as the currently marketed and predicate device, Ingenuity TF Digital PET/CT (K123599).

The design, and the fundamental scientific technology provided with the proposed Vereos PET/CT System is identical to the currently marketed and predicate device, Ingenuity TF Digital PET/CT (K123599).

This 510(k) submission addresses the changes that have been made since the clearance of the predicate device Ingenuity TF Digital PET/CT. The following changes do not impact device safety and effectiveness.

- CT Slice Thickness (Reconstruction) is changed from 0.5-12mm to 0.5-15 mm. 0.5 mm is available using 2x0.5 mm collimation with Ultra-High resolution mode in an axial scan. 15 mm is available using 12x1.25 mm collimation with CCT protocol. 15 mm is introduced with iPatient software which is carried from the CT sub-system Ingenuity CT (cleared under K160743). The CT Gantry (Ingenuity CT) for the proposed Vereos PET/CT is identical to the Philips Ingenuity CT System (cleared under K160743).
- Increase in the operating temperature of the PET detector tiles. Raising the operating temperature mitigates the risk of condensation on the detector tiles, while improving the reliability of the PET cooling system.
- Change in system sensitivity from ≥ 5.5 cps/kBq to ≥ 5.1 cps/kBq. The change in the system sensitivity requirements are mainly from the increasing the operating temperature of the PET detection. Image quality assessment during the system verification determined that the image quality was acceptable and no recognizable artifacts were identified.
- Scatter Fraction per NEMA NU-2 standard was changed from ≤ 30% to ≤ 35%. The system meets the essential performance threshold for NEMA NU2 scatter fraction of less than or equal to 46%. This change is a refinement of the requirement based on verification testing data and this change is acceptable without affecting system performance.
- Software defect fixes for the startup conditions and change humidity and temperature requirements to restart the system.
- Cardiac scan reconstruction tagging defect fix by releasing a software patch. This software patch was verified and the verification results indicated that there are no changes in safety and performance of the proposed Vereos PET/CT.
- New Detector material LSO (Lutetium Oxyorthosilicate) Crystal is added in addition to LYSO (Lutetium-yttrium Oxyorthosilicate) Crystal. Both of these crystals are from the LTS (Lutetium Scintillator) family. The proposed Vereos PET/CT user manual will identify LTS as a general crystal material family. The purpose of this change is to reduce cost. The change in crystal has been verified for the requirements set for Spatial Resolution, Sensitivity, Scatter Fraction Count Losses and Randoms Measurement and Corrections, Image Quality, Accuracy of Attenuation and scatter Corrections. The verification results indicated that there are no changes in safety and performance of the proposed Vereos PET/CT.
- Material changes have been made to comply with EU RoHS Directive.
- <u>Hardware Changes:</u>
  - A new industrial cover design with unified CT and PET gantries.
  - Minor modifications to gantry cover design: The Cover design corrections include addition of mechanical parts for the purpose of resolving internal interferences to hatchback and CT window,

hinge/mounting improvements for the front and rear cover, and centering to the Gantry bore.
    - Couch Horizontal Maximum speed was changed from 170 mm/s to 185 mm/s. This change is does not impact clinical performance of the device. The couch design is fully compliant to IEC 60601-1 and 60601-2-44 standards.
    - Couch Drive Chain and 10 mm stop distance design changes to improve reliability and audible noise reduction of the couch. There are no changes to performance requirements.
    - For better serviceability, minor design change for catcher is implemented. Catcher is used to limit the amount of patient pallet deformation and is mounted at the other side of the PET/CT Gantry to provide support to the patient pallet once it travels beyond the PET FOV.
- Compliance to latest edition of IEC 60601 series of standards.
- Minor modification changes include labelling clarification, hardware obsolescence issues and software defect fixes/improvements, manufacturability, reliability and serviceability improvements that were implemented since clearance of the predicate device. These changes do not impact device safety and effectiveness.

Based on the information provided above, the proposed Vereos PET/CT System is considered substantially equivalent to the currently marketed and predicate device Ingenuity TF Digital PET/CT System (K123599), in terms of fundamental scientific technology.

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 demonstrates 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.

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) (FDA Recognition Number: 19-4)
- IEC 60601-1-2:2014: (FDA Reorganization Number :19-8)
- IEC 60601-1-3:2008+A1:2013 (FDA Recognition Number: 12-269)
- IEC 60601-1-6:2010 +A1: 2013 (FDA Recognition Number: 5-89)
- IEC 60601-2-44:2009/AMD2:2016 (FDA Recognition Number: 12-302)
- IEC 62304:2006 + A1: 2015 (FDA Recognition Number: 13-79)
- IEC 60825-1:2014 (Pursuant to FDA Laser Notice 56 (May 2019)
- IEC 62366-1:2015 (FDA Recognition Number: 5-114)
- IEC 60601-2-28:2017 (FDA Recognition Number: 12-309)
- ISO 10993-1 (FDA Recognition Number: 2-258)
- ISO 14971 2nd Edition. (FDA Recognition Number: 5-40)

Additionally, the proposed Vereos PET/CT was tested against NEMA NU-2:2012, Performance Measurement of Positron Emission Tomographs.

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).

Design Verification planning and testing was conducted at the sub-system and at the system level. The sub-systems are tested against the sub-system requirements specifications (SSRS) and the system level verification is conducted against the system requirement specifications (SRS). System and sub-system verification activities demonstrate the system or sub-systems meet the established system and sub-system level design input requirements. System and sub-system level requirements may be verified by manual test, automated test, inspection/analysis, or any combination of the three. Design verification also includes Image Quality verification and risk analysis risk mitigation testing.

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 per 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 covered the intended use and commercial claims as well as usability testing with representative intended users. Validation testing included clinical workflow validation and service validation.

All these tests were used to support substantial equivalence of the proposed Vereos PET/CT System and demonstrate that the proposed Vereos PET/CT System

- 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 Vereos PET/CT system is substantially equivalent to the currently marketed and predicate device Ingenuity TF Digital PET/CT (K123599) under in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The proposed Vereos PET/CT system did not require any external clinical study. The clinical evaluation of workflow was conducted via simulated use testing and is accounted for in the summary of "Non-Clinical Testing" section of the summary. The substantial equivalence to the currently marketed and predicate device Ingenuity Digital PET/CT (K123599) was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- 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 good image quality.

Substantial Equivalence Conclusion:

The proposed Vereos PET/CT System is substantially equivalent to the currently marketed predicate device Ingenuity TF Digital PET/CT (K123599) in terms of

design, features and fundamental scientific technology. There was no change in Intended Use/Indication for Use.

Additionally, substantial equivalence was demonstrated by non-clinical (verification and validation) performance tests provided in this 510(k) premarket notification. These tests demonstrate that proposed Vereos PET/CT system complies with the requirements specified by Philips Medical Systems Nederland B.V. and the international and FDA-recognized consensus standards and is as safe and effective as its currently marketed and predicate device Ingenuity TF Digital PET/CT (K123599) without raising any new safety and/or effectiveness concerns.