Siemens Medical Solution USA, Inc.
% Alaine Medio
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE TN 37932

February 12, 2020

Re: K193178
Trade/Device Name: Biograph Horizon PET/CT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: January 16, 2020
Received: Janu 17, 2020

Dear Alaine Medio:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193178

Device Name
Biograph Horizon PET/CT

Indications for Use *(Describe)*

The Siemens Biograph Horizon PET/CT systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging. These systems are intended to be utilized by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and re staging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

This CT system can be used for low dose lung cancer screening in high risk populations.*

* As defined by professional medical societies. 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.

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510(k) Summary - K193178

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter:	M. Alaine Medio, RAC Regulatory Affairs Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Alternative Contact:	Tabitha Estes Regulatory Affairs
Manufacturer:	Siemens Medical Solutions USA, Inc. Molecular Imaging 2501 North Barrington Road Hoffman Estates, IL 60192
Telephone Number:	(865)206-0337
Fax Number:	(865)218-3019
Date of Submission:	November 12, 2019

Identification of the product

Device Proprietary Name:	Biograph Horizon PET/CT
Common Name:	Positron Emission Tomography (PET) System Computed Tomography (CT) System
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200 Computed Tomography X-Ray System per 21 CFR 892.1750
Product Code:	KPS and JAK
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Predicate:

Device Proprietary Name:	Biograph Horizon PET/CT Systems
Manufacturer:	Siemens Medical Solutions USA, Inc.
Product Code:	KPS and JAK
Device Class:	Class II
510(k) Number:	K170904

Reference Devices:

Device Name and 510(k) numbers:	Biograph mCT PET/CT systems	K173578
	Biograph Vision PET/CT systems	K190900
	SOMATOM Perspective CT	K183548

Device Description:

The Biograph Horizon PET/CT systems are combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanners. These systems are designed for whole body oncology, neurology and cardiology examinations. The Biograph Horizon systems provide registration and fusion of high-resolution metabolic and anatomic information from the two major components of each system (PET and CT). Additional components of the system include a patient handling system and acquisition and processing workstations with associated software.

Biograph Horizon software is a command-based program used for patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements.

The software for the Biograph Horizon systems which is the subject of this application is substantially equivalent to the commercially available Biograph Horizon software. Modifications include, corrections to software anomalies and addition of new software features, including:

- OncoFreeze
- OncoFreeze AI (Data Driven Gating)
- CardioFreeze
- FlowMotion Multi-Parametric PET AI

- PET FAST Planning (FlowMotion AI)
- FAST PET Workflow
- QualityGuard
- Updates to HD FoV
- Updates to PET DICOM dose Report
- Whole Body Scatter Correction

Additionally, minor modifications have been made to the computers due to obsolescence issues and to the controllers of the PHS for cost improvement. These changes do not affect system performance characteristics and have no impact on safety or effectiveness.

Intended Use:

The Siemens Biograph Horizon systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging.

These systems are intended to be utilized by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. 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.

Performance Testing / Safety and Effectiveness:

Performance testing for the CT subsystem was included in the original premarket notification for the CT subsystems and there have been no changes affecting this testing.

PET Testing in accordance with NEMA NU2-2018 was conducted on two different configurations of the Biograph Horizon systems, a 3-ring version and a 4-ring version (TrueV).

Performance Criteria	Results	Acceptance
Resolution – Full Size		
Transverse Resolution FWHM @ 1 cm	Pass	≤ 4.7 mm
Transverse Resolution FWHM @ 10 cm	Pass	≤ 5.5 mm
Transverse Resolution FWHM @ 20 cm	Pass	≤ 7.6 mm
Axial Resolution FWHM @ 1 cm	Pass	≤ 5.0 mm
Axial Resolution FWHM @ 10 cm	Pass	≤ 7.0 mm
Axial Resolution FWHM @ 20 cm	Pass	≤ 11.3 mm
Resolution – 256 x 256		
Transverse Resolution FWHM @ 1 cm	Pass	≤ 7.3 mm
Transverse Resolution FWHM @ 10 cm	Pass	≤ 7.6 mm
Transverse Resolution FWHM @ 20 cm	Pass	≤ 8.9 mm
Axial Resolution FWHM @ 1 cm	Pass	≤ 6.1 mm
Axial Resolution FWHM @ 10 cm	Pass	≤ 7.3 mm
Axial Resolution FWHM @ 20 cm	Pass	≤ 11.9 mm
Count Rate / Scatter / Sensitivity		
Sensitivity @435 keV LLD	Pass	≥ 5.8 cps/kBq ≥ 10.9 cps/kBq (TrueV)
Count Rate peak NECR	Pass	≥ 78 kcps @ ≤ 26 kBq/cc ≥ 135 kcps @ ≤ 26 kBq/cc (TrueV)
Count Rate peak trues	Pass	≥285 kcps @ ≤ 53 kBq/cc ≥ 465 kcps @ ≤ 42 kBq/cc (TrueV)
Scatter Fraction at peak NECR	Pass	≤ 40%
Mean bias (%) at peak NEC	Pass	≤ +/- 6%
Image Quality (4 to 1) - (% Contrast / Background Variability)		
10mm sphere	Pass	≥ 10% / ≤ 10%
13mm sphere	Pass	≥ 25% / ≤ 10%
17mm sphere	Pass	≥ 40% / ≤ 10%
22mm sphere	Pass	≥ 55% / ≤ 10%
28mm sphere	Pass	≥ 60% / ≤ 10%
37mm sphere	Pass	≥ 65% / ≤ 10%
Co-Registration Accuracy		
Max Error	Pass	≤ 5 mm

All features (including the new features listed in device description) were tested during Verification and Validation testing and met the predetermined acceptance criteria.

Further, the changes below had additional scientific evaluations performed. A brief description of testing activities is provided.

- OncoFreeze AI (Data Driven Gating) - An evaluation of change in SUVmax, SUVmean and Volume measurement has been performed in motion-corrected (OncoFreeze) images comparing Anzai based gating and deviceless gating.

	Anzai-based OncoFreeze	Deviceless OncoFreeze
ΔSUV_{max} (relative to static)	+29% ± 22%	+27% ± 22%
ΔSUV_{mean} (relative to static)	+27% ± 22%	+26% ± 22%
ΔVolume (relative to static)	-34% ± 23%	-31% ± 19%

- OncoFreeze / CardioFreeze – These features were shown to enable each individual gate to be reconstructed using 100% of the counts – 24x more in each individual gate than conventional dual gating (assuming 8 cardiac gates and a duty cycle of 35%).
- FlowMotion Multi-Parametric PET AI – Comparison of Patlak transformation on a series of dynamic PET images on a voxel by voxel basis in image space versus performing the Patlak transformation during reconstruction using the automatic feature showed improved noise characteristics and better delineation of organs and tumors when using the Patlak during reconstruction.
- FlowMotion AI (PET FAST Planning) – Testing was performed to evaluate the accuracy with which FlowMotion AI correctly defined the bed ranges. Successful identification of all ranges in a FlowMotion AI configuration ranged from 87.1% to 100%, dependent on the configuration set.
- QualityGuard – Use of Quality Guard demonstrated a time savings of up to 30 minutes / day as well as reducing staff exposure to calibration sources by up to 98%.
- Whole Body Scatter Correction - An evaluation was performed to evaluate ROIs using Single Bed Scatter compared to whole body scatter correction.

Difference from ground truth In simulation study of phantom	Single Bed Scatter Correction	Whole Body Scatter correction
Representative region of interest close to phantom exhibiting high signal	+87%	-2%
Representative region of interest close to phantom exhibiting low signal	-42%	-3%
Representative region of interest inside phantom	+0.5%	-0.4%

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions, USA Inc. adheres to recognized and established industry standards such as IEC 60601-1 series and 21 CFR 1020.30 and 21 CFR 1020.33 to minimize electrical, mechanical and radiation hazards.

Siemens claims compliance with the following product standards for the Biograph Horizon:

- IEC 60601-1: 2005+ A1:2012
- IEC 60601-1-2: 2014
- IEC 60601-1-3: 2013
- IEC 60601-1-6:2010 +A1:2013
- IEC 60601-2-28:2010
- IEC 60601-2-44: 2009 + A1:2012
- IEC 62366-1:2015
- IEC 61223-2-6:2006
- IEC 61223-3-5:2004
- NEMA XR 25: 2010
- NEMA XR 28: 2013
- NEMA XR 29: 2013
- NEMA PS3.1-3.20

Additionally, the Biograph Horizon has been developed in accordance with the requirements of the following standards:

- IEC 62304:2006 +A1:2015
- ISO 14971:2012 (ISO 14971:2007)

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Cybersecurity information in accordance with FDA Guidance documents issued October 2, 2014 has been provided. The Biograph Horizon software has specific cybersecurity controls to prevent unauthorized access, modifications, misuse or denial of use. Additionally, controls are enabled to prevent the unauthorized use of information that is stored, accessed or transferred between the Biograph Horizon and external devices.

Verification and validation of Siemens systems is performed in accordance with documented procedures, design and code reviews, test plans and specifications. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

Statement regarding Substantial Equivalence:

There have been no changes implemented in the modifications to the Biograph Horizon that impact either the fundamental technology or the indications for use. The Biograph Horizon with the modifications outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate device.