



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Alaine Medio
PET and PCS Regulatory Projects Manager
810 Innovation Drive
KNOXVILLE TN 37932

January 12, 2016

Re: K152880

Trade/Device Name: Biograph Horizon PET/CT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: December 1, 2015
Received: December 2, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152880

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 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter: M. Elaine Medio, RAC
PET and PCS Regulatory Projects Manager
Siemens Medical Solutions USA, Inc.
Molecular Imaging
810 Innovation Drive
Knoxville, TN 37932

Manufacturers: Siemens Medical Solutions USA, Inc.
Molecular Imaging
810 Innovation Drive
Knoxville, TN 37932

Siemens Medical Solutions USA, Inc.
Molecular Imaging
2501 North Barrington Road
Hoffman Estates, IL 60192

Telephone Number: (865)218-2703

Fax Number: (865)218-3019

Date of Submission: September 29th, 2015

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: 90 KPS and 90 JAK

Classification Panel: Radiology

Device Class: Class II

Marketed Devices to which Equivalence is claimed

Predicate:

Device Proprietary Name: Biograph mCT PET/CT
Manufacturer: Siemens Medical Solutions USA, Inc.
Product Code: 90 KPS and 90 JAK
Device Class: Class II
510(k) Number: K151486

Reference Devices:

Device Name: Somatom Perspective
510(k) Numbers: K133590

Device Description:

The Biograph Horizon PET/CT system is a combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanners. This system is designed for whole body oncology, neurology and cardiology examinations. The Biograph Horizon scanners 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 Biograph Horizon system which is the subject of this application is substantially equivalent to the commercially available Biograph mCT family of PET/CT systems (K151486). Differences compared to the Biograph mCT include:

- The PET subsystem has been modified to provide for an air-cooled only PET system with a 70 cm bore size. The detectors, electronics, etc... are substantially equivalent to the current Biograph mCT system.
- The commercially available Perspective 16 slice system (K133590) has been incorporated as the CT subsystem for the Biograph Horizon.
- The software integrated into the Biograph Horizon systems is based upon the mCT software and includes a subset of features that are commercially available with the Biograph mCT systems. Major updates to the software system for use on the Biograph Horizon include:
 - limiting of high end features available with the mCT

- changes in software to support the modified PET and CT subsystems
- updates for workflow and anomaly corrections.

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.

Performance Testing / Safety and Effectiveness:

PET Testing in accordance with NEMA NU2:2012 was conducted on two different configurations of the Biograph Horizon PET/CT systems, a 3 ring version and a 4 ring version.

Performance Criteria	Results (Average)	Acceptance (Standard PET)	Acceptance (TrueV PET)
Resolution – Full Size			
Transverse Resolution FWHM @ 1 cm	Pass	$\leq 4.7\text{ mm}$	$\leq 4.7\text{ mm}$
Transverse Resolution FWHM @ 10 cm	Pass	$\leq 5.5\text{ mm}$	$\leq 5.5\text{ mm}$
Transverse Resolution FWHM @ 20 cm	Pass	$\leq 7.6\text{ mm}$	$\leq 7.6\text{ mm}$
Axial Resolution FWHM @ 1 cm	Pass	$\leq 5.0\text{ mm}$	$\leq 5.0\text{ mm}$
Axial Resolution FWHM @ 10 cm	Pass	$\leq 7.0\text{ mm}$	$\leq 7.0\text{ mm}$
Axial Resolution FWHM @ 20 cm	Pass	$\leq 11.3\text{ mm}$	$\leq 11.3\text{ mm}$
Resolution – 256 x 256			
Transverse Resolution FWHM @ 1 cm	Pass	$\leq 7.3\text{ mm}$	$\leq 7.3\text{ mm}$
Transverse Resolution FWHM @ 10 cm	Pass	$\leq 7.6\text{ mm}$	$\leq 7.6\text{ mm}$
Transverse Resolution FWHM @ 20 cm	Pass	$\leq 8.9\text{ mm}$	$\leq 8.9\text{ mm}$
Axial Resolution FWHM @ 1 cm	Pass	$\leq 6.1\text{ mm}$	$\leq 6.1\text{ mm}$
Axial Resolution FWHM @ 10 cm	Pass	$\leq 7.3\text{ mm}$	$\leq 7.3\text{ mm}$
Axial Resolution FWHM @ 20 cm	Pass	$\leq 11.9\text{ mm}$	$\leq 11.9\text{ mm}$

Performance Criteria	Results (Average)	Acceptance (Standard PET)	Acceptance (TrueV PET)
Sensitivity @435 keV LLD	Pass	≥ 5.8 cps/MBq	≥ 10.9 cps/MBq
Count Rate peak NECR	Pass	≥ 78 kcps @ ≤ 26 kBq/cc	≥ 135 kcps @ ≤ 26 kBq/cc
Count Rate peak trues	Pass	≥ 285 kcps @ ≤ 53 kBq/cc	≥ 465 kcps @ ≤ 42 kBq/cc
Scatter Fraction at peak NECR	Pass	$\leq 40\%$	$\leq 40\%$
Mean bias (%) at peak NEC	Pass	≤ 6	≤ 6

CT Testing in accordance with the requirements of the following FDA Performance Standards for Ionizing Radiation Emitting Products and Light emitting products for CT equipment with a laser localizer was performed and documented in a Dosimetry and Imaging Performance Report. Further, each CT subsystem is tested and passes the Applicable Performance Standards prior to shipment:

- 21 CFR 1020.30 (a) Applicability
- 21 CFR 1020.30 (b)(36)(iii)-(v) Technique factors
- 21 CFR 1020.30 (b)(58)-(62) CT, Scan, Scan Time, Tomogram, Dose
- 21 CFR 1020.30 (h)(3)(vi)-(viii) Information to be provided for users
- 21 CFR 1020.33 Computed Tomography (CT) equipment
- 21 CFR 1040.10 Laser Products
- 21 CFR 1040.11 Specific purpose laser products

The Biograph Horizon PET/CT system was designed in accordance with Design Controls and in accordance with the following FDA recognized standards:

- Recognition Number 19-1: IEC 60601-1-2 Edition 3: 2007-03
- Recognition Number 19-4: AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012
- Recognition Number 5-85: IEC 60601-1-6 Edition 3.0 2010-01
- Recognition Number 12-256: IEC 60601-2-44 Edition 3.1 2012-09
- Recognition Number 12-269: IEC 60601-1-3 Edition 2.1 2013-04
- Recognition Number 5-40: ISO 14971 Second Edition 2007-03
- Recognition Number 13-8: IEC 62304 First Edition 2006-05
- Recognition Number 12-265: NEMA NU 2-2012
- Recognition Number 12-238: NEMA PS 3.1 - 3.20 (2011)
- Recognition Number 12-225: NEMA XR 25
- Recognition Number 12- 270: NEMA 61223-3-5 First Edition 2004
- Recognition Number 12-226: NEMA 61223-2-6 Second Edition: 2006

All Performance testing performed met the predetermined acceptance values.

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.

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:

The Biograph Horizon PET/CT is based on the commercially available Biograph mCT Family of PET/CT scanners. There is no difference in Indications for use, nor is there any change in fundamental scientific technology as compared to the predicate device. The software and device features are a subset of the predicate device features, and pose no new questions of safety and / or efficacy.

Based on the information provided in the Premarket Notification Siemens Medical Solutions USA, Inc. considers the Biograph Horizon PET/CT system described in this Premarket Notification to be substantially equivalent to the currently commercially available predicate device.