



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

October 25, 2016

Re: K162736
Trade/Device Name: Biograph Horizon PET/CT Systems
Biograph mCT PET/CT and Biograph mCT Flow PET/CT Systems
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: September 29, 2016
Received: September 30, 2016

Dear Mr. 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, faint, light-blue watermark of the FDA logo.

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)

K162736

Device Name

Biograph Horizon PET/CT Systems

Biograph mCT PET/CT and Biograph mCT Flow PET/CT Systems

Indications for Use (Describe)

The Siemens Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.

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510(k) Summary
as required by 21 CFR Part 807.92

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

Manufacturer: Siemens Medical Solutions USA, Inc.
Molecular Imaging
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Hoffman Estates, IL 60192

Telephone Number: (865)218-2703

Fax Number: (865)218-3019

Date of Submission: September 29th, 2016

Identification of the product

Device Proprietary Name:	Biograph Horizon PET/CT Systems	Biograph mCT PET/CT and Biograph mCT Flow PET/CT Systems
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 Horizon PET/CT Systems
Manufacturer: Siemens Medical Solutions USA, Inc.
Product Code: 90 KPS and JAK
Device Class: Class II
510(k) Number: K152880

Reference Devices:

Device Proprietary Name:	Biograph mCT PET/CT and Biograph mCT Flow PET/CT Systems	SOMATOM CT Scanners
510(k) :	K151486	K142955

Device Description:

The Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems are 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 PET/CT systems and Biograph mCT and mCT Flow PET/CT 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.

The 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 PET/CT systems and Biograph mCT and mCT Flow PET/CT systems that are the subject of this Premarket Notification are identical in design, material, functionality, technology and energy source to the commercially available Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems.

Intended Use:

The Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems are radiological imaging systems that are a combination of a positron emission tomography (PET) camera system for nuclear medicine images, and a computed tomography (CT) camera

system for x-ray images. The nuclear medicine images and the x-ray images may be registered and displayed in a fused format (overlaid in the same orientation) for the anatomical localization of the nuclear medicine data (i.e., distribution of radiopharmaceuticals). The PET and CT portions of the system may be used independently or in combination. The PET and CT images may be transferred to other systems for radiation therapy planning or additional processing.

This submission was made to support an additional indication for use related to lung cancer screening within the subset of the overall intended use of the Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems:

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.

This revised indication for use is cleared for the standalone SOMATOM CT systems (K142955) that are incorporated into the Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems.

In accordance with guidance document "Guidance for Industry. General/Specific Intended Use" issued November 4, 1998, and presentation "FDA/MITA Meeting on LDCT Lung Cancer Screening", the modified more specific indication for use does not alter the intended use for the legally marketed predicate devices with a general indication for use, nor does it alter the intended diagnostic effect in comparison to the predicate devices.

Based on the analysis conducted within the original 510(k) for the SOMATOM CT systems (K142955) and the integration of the CT subsystem, without altering the technological characteristics, into the Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems, the more specific use of low dose lung cancer screening is a subset of the general use rather than a new intended use. Further, the updated specific indication is substantially equivalent to the inclusion of this specific indication within the predicate device.

Revised Indications for Use:

The Siemens Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow 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.

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:

The Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems that are the subject of this Premarket Notification are identical in design, material, functionality, technology and energy source to the commercially available Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems. No additional performance testing beyond what was cleared in the original Premarket Notifications is required.

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 systems and Biograph mCT and mCT Flow PET/CT systems were 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 5-89: IEC 60601-1-6 Edition 3.1 2013-10
 - 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 13-79: IEC 62304 Edition 1.1 2015-06
 - Recognition Number 12-265: NEMA NU 2-2012
 - Recognition Number 12-300: NEMA PS 3.1 - 3.20 (2016)
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- 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

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.

Technical parameters used to test general CT use are applicable for lung cancer screening. The technical parameters of the CT subsystem for the Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems and the commercially available SOMATOM standalone CT systems devices with the additional lung cancer screening indication (K142955) were compared, and no differences exist in the parameters. Included in this evaluation, are the following parameters:

- CT number accuracy
- CT number uniformity
- Spatial resolution (MTF, maximum in-plane resolution)
- Slice thickness/sensitivity profile (minimum slice width)
- Noise properties (NPS and image Noise (standard deviation))
- Contrast to Noise Ratio
- Maximum scan speed
- Minimum reconstructed slice interval

The test results demonstrate that the subject devices perform the same as the standalone SOMATOM CT systems. Since the standalone systems have been identified as suitable for lung cancer screening (K142955), the use of the CT component of the Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems is likewise suitable for lung cancer screening.

Statement regarding Substantial Equivalence:

The Biograph Horizon PET/CT Systems and Biograph mCT and mCT Flow PET/CT systems are commercially available and no changes to technological, functional or clinical features have been made. There is no difference in the intended use of the device. The CT systems being referenced as predicate devices (K14955) are integrated into the PET/CT systems as a subsystem of the device and no differences in functionality have been made compared to the commercially available systems (with the exception of the removal of the tilt functionality). All parameters associated with low dose lung cancer screening are the same between the devices subject to this application and the predicate devices referenced.

Based on the information provided in the Premarket Notification, Siemens Medical Solutions USA, Inc. considers the Biograph Horizon PET/CT systems and Biograph mCT and mCT Flow PET/CT systems with the added low dose lung cancer screening indication to be substantially equivalent to the currently commercially available predicate device.