



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

May 23, 2018

Re: K180811

Trade/Device Name: Biograph Vision PET/CT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: March 28, 2018
Received: March 29, 2018

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Michael D. O'Hara 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)

K180811

Device Name

Biograph Vision PET/CT

Indications for Use (Describe)

The Siemens Biograph Vision 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter: Alaine Medio
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)218-2703

Fax Number: (865)218-3019

Date of Submission: March 28,2018

Identification of the product

Device Proprietary Name: Biograph Vision 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 Family of PET/CT Systems
Manufacturer:	Siemens Medical Solutions USA, Inc.
Product Code:	90 KPS and 90 JAK
Device Class:	Class II
510(k) Number:	K173578

Reference Devices:

Device Name:	Discovery MI
510(k) Number:	K161574
Device Name:	Ingenuity Digital PET/CT System
510(k) Number:	K123599

Device Description:

The Biograph Vision systems are combined multi-slice X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners. These systems are designed for whole body oncology, neurology and cardiology examinations.

The Biograph Vision 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 Vision 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 Vision PET/CT, which is the subject of this application, is substantially equivalent to the commercially available Biograph mCT (K173578). The key difference between the Biograph mCT (predicate device) and the Biograph Vision PET/CT is the replacement of PhotoMultiplier Tubes (PMT) with Silicon PhotoMultipliers (SiPM). SiPMs are a photon sensitive technology built by combining a solid state photodiode array and a silicon substrate. The SiPMs allow close coupling to the scintillators (crystals) and a higher active area of detectors to scintillators. This combination results in superior performance compared to the photomultiplier tubes design used in previous generation PET block detectors.

Intended Use:

The Biograph Vision PET/CT systems are radiological imaging system 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.

Indications for Use

The Siemens Biograph Vision 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.

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*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:

PET Testing in accordance with NEMA NU2:2012 was conducted on the Biograph Vision 600.

Performance Criteria	Results	Acceptance
Resolution – Full Size		
Transverse Resolution FWHM @ 1 cm	Pass	≤ 4.0 mm
Transverse Resolution FWHM @ 10 cm	Pass	≤ 4.8 mm
Transverse Resolution FWHM @ 20 cm	Pass	≤ 5.2 mm
Axial Resolution FWHM @ 1 cm	Pass	≤ 4.3 mm
Axial Resolution FWHM @ 10 cm	Pass	≤ 5.4 mm
Axial Resolution FWHM @ 20 cm	Pass	≤ 5.4 mm
Count Rate / Scatter / Sensitivity		
Sensitivity @435 keV LLD	Pass	≥ 15.0 cps/kBq
Count Rate peak NECR	Pass	≥250 kcps @ ≤ 32 kBq/cc
Count Rate peak trues	Pass	≥1100 kcps @ ≤ 56 kBq/cc
Scatter Fraction at peak NECR	Pass	≤43%
Mean bias (%) at peak NEC	Pass	≤ 6%
Image Quality (4 to 1) - (% Contrast / Background Variability)		
10mm sphere	Pass	≥ 55% / ≤ 10%
13mm sphere	Pass	≥ 60% / ≤ 9%
17mm sphere	Pass	≥ 65% / ≤ 8%
22mm sphere	Pass	≥ 70% / ≤ 7%
28mm sphere	Pass	≥ 75% / ≤ 6%
37mm sphere	Pass	≥ 80% / ≤ 5%

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.

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 Vision:

- 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 + A2:2016

- 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 Vision 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 Vision 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 Vision 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.

All Performance testing met the predetermined acceptance values. This, coupled with the successful verification and validation testing demonstrates that the Biograph Vision functions as intended and that performance is comparable to the predicate devices.

Statement regarding Substantial Equivalence:

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