Siemens Medical Solutions USA, Inc.
% Ms. Tabitha Estes
Regulatory Technical Specialist
810 Innovation Drive
KNOXVILLE TN 37932

December 20, 2017

Re: K173578
Trade/Device Name: Biograph mCT and MCT Flow PET/CT Scanners
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: November 17, 2017
Received: November 21, 2017

Dear Ms. Estes:

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.

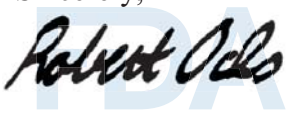
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K173578

Device Name
Biograph mCT and mCT Flow PET/CT Scanners

Indications for Use *(Describe)*
Siemens mCT 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 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 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 healthcare 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. (High risk population has been 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.

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
PRAStaff@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:	Tabitha Estes Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Manufacturer:	Siemens Medical Solutions USA, Inc. Molecular Imaging 2501 North Barrington Road Hoffman Estates, IL 60192
Telephone Number:	(865)218-2421
Fax Number:	(865)218-3019
Date of Submission:	November 17th, 2017

Identification of the product

Device Proprietary Name:	Biograph mCT Family of 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 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:	K151486

Reference Devices:

Device Name:	Somatom Definition AS/AS+/Edge
510(k) Numbers:	K152036 (Somatom Definition AS/AS+/Edge)

Device Name:	Biograph Horizon
510(k) Number:	K170904

Device Description:

The Biograph mCT family 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 mCT 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 mCT 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 mCT systems which is the subject of this application is substantially equivalent to the commercially available Biograph mCT software. Modifications include:

- Somaris Software (cleared in K152036)
    - Upgrade to the latest revision of Somaris Software
- PETsyngo software
    - Update of the software to add Low CT Does Protocols for PET AC
    - Update to add Wholebody Scatter Correction
    - QualityGuard
    - FlowMotion Multi-Parametric PET
    - OncoFreeze
    - CardioFreeze
    - Shuttle Mode PET Acquisition
    - Parallel Reconstruction
    - PET Dose Report
    - TeamViewer
    - Maximum Patient Clearance Mode
    - Smart Mobile Connect
    - Update of the software corrections
    - Update of the TrueD software component
        - Address anomalies
        - Update to improve usability and viewing of Multi-Parametric PET images
    - Improvements to workflow
    - Improvements to performance (faster reconstruction speeds)

Intended Use:

The Siemens Biograph mCT 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.

The Siemens Biograph mCT 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 NU2:2012 was conducted on two different configurations of the Biograph mCT systems, a 3 ring version and a 4 ring version.

Performance Criteria	Results	Acceptance
Resolution – Full Size		
Transverse Resolution FWHM @ 1 cm	Pass	≤ 4.7 mm
Transverse Resolution FWHM @ 10 cm	Pass	≤ 5.4 mm
Transverse Resolution FWHM @ 20 cm	Pass	≤ 6.3 mm
Axial Resolution FWHM @ 1 cm	Pass	≤ 4.9 mm
Axial Resolution FWHM @ 10 cm	Pass	≤ 6.5 mm
Axial Resolution FWHM @ 20 cm	Pass	≤ 8.8 mm
Resolution – 256 x 256		
Transverse Resolution FWHM @ 1 cm	Pass	≤ 7.3 mm
Transverse Resolution FWHM @ 10 cm	Pass	≤ 7.5 mm
Transverse Resolution FWHM @ 20 cm	Pass	≤ 7.7 mm
Axial Resolution FWHM @ 1 cm	Pass	≤ 6.0 mm
Axial Resolution FWHM @ 10 cm	Pass	≤ 6.6 mm
Axial Resolution FWHM @ 20 cm	Pass	≤ 9.2 mm
Count Rate / Scatter / Sensitivity		
Sensitivity @435 keV LLD	Pass	≥ 5.0 cps/kBq ≥ 9.4 cps/kBq (TrueV)
Count Rate peak NECR	Pass	≥ 95 kcps @ ≤ 30 kBq/cc ≥ 165 kcps @ ≤ 28 kBq/cc (TrueV)
Count Rate peak trues	Pass	≥350 kcps @ ≤ 46 kBq/cc ≥ 575 kcps @ ≤ 40 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	≥ 55% / ≤ 10%
37mm sphere	Pass	≥ 60% / ≤ 10%

All Performance testing 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:

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