DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

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

September 12, 2014

Re: K141971
Trade/Device Name: Biograph TruePoint PET/CT Family Software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: August 26, 2014
Received: August 27, 2014

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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141971

Device Name
Biograph TruePoint PET/CT Family Software

Indications for Use *(Describe)*

The Siemens Biograph TruePoint 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)

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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"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) and 807.92 (c)

Identification of the Submitter

Submitter:	M. Alaine Medio, RAC PET and PCS Regulatory Projects Manager Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Telephone Number:	(865)218-2703
Fax Number:	(865)218-3019

Date of Submission:	September 3, 2014

Identification of the product

Device Proprietary Name:	Biograph TruePoint PET/CT Family Software
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	Manufacturer	510(k) Number
Primary Predicate	Biograph mCT Family PET/CT scanner software	Siemens Medical Solutions USA, Inc	K123737
Reference Predicate	Biograph TruePoint PET/CT scanner software	Siemens Medical Solutions USA, Inc	K083852

Device Description:

The Biograph TruePoint Family of 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 TruePoint 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 TruePoint PET/CT Family 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 updates to the Biograph TruePoint systems software which are the subject of this application are considered substantially equivalent to the commercially available Biograph TruePoint software. Major modifications to the family of systems include:

- General
    - Update of the operating system to Windows 7 for the ACS and PRS components for improved sustainability
    - Support for SolidCore – implemented for change protection and software security.
    - updates to address anomalies for CT and PET software
- syngo software upgrade
    - Update of the syngo software to the latest revision (drivers, etc...)
- Somaris Software Update
    - Upgrade to the latest revision Somaris Software (VB42) (K140232)
    - Inclusion of MITA Dose check features to be compliant with the MITA dose requirements. Dose Notification and Dose Alert; Dose Logs; Access and CARE Analytics, CARE Dose 4D etc...
    - Improvements to scanning and reconstruction workflows
- PETsyngo software
    - Update of software to provide for improved consistency of features between all TruePoint models
    - Update to add Variable Bed Time
    - Update of the software scatter correction and bed removal
    - Update of the TrueD software
    - Improvements to the service tools
    - Improvements to workflow

Intended Use:

The Siemens Biograph TruePoint 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.

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Technological Characteristics

The Biograph TruePoint PET/CT Family software with modifications is based on the commercially available Biograph TruePoint and Biograph mCT Family software. There has been no introduction of features that are not already commercially available in the predicate systems introduced with these software modifications. All software has technological characteristics consistent with the predicate software.

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 NU2:2007 was conducted on two different configurations of the Biograph TruePoint systems, a 3 ring version and a 4 ring version.

Performance Criteria (Standard)	Results	Acceptance
Transverse Resolution FWHM @ 1 cm	Pass	</= 6.5 mm
Transverse Resolution FWHM @ 10 cm	Pass	</= 6.5 mm
Axial Resolution FWHM @ 1 cm	Pass	</= 6.0 mm
Axial Resolution FWHM @ 10 cm	Pass	</= 6.5 mm
Sensitivity @435 keV LLD	Pass	>/= 4.0 cps/kBq (3R) >/= 7.0 cps/kBq (4R)
Count Rate peak NECR	Pass	86 kcps @ 42 kBq/cc (3R) 148 kcps@ 42 kBq/cc (4R)
Count Rate peak trues	Pass	306 kcps @ 42 kBq/cc (3R) 467 kcps @ 42 kBq/cc (4R)
Count Rate bias (mean)	Pass	<= 7%
Scatter Fraction	Pass	<38%

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 TruePoint PET/CT Family software that impact either the fundamental technology or the indications for use. The Biograph TruePoint software with the modifications outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate device.