

K113448

DEC 17 2011

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

Telephone Number: (865)218-2703

Fax Number: (865)218-3019

Date of Submission: November 18, 2011

Identification of the product

Device Proprietary Name: Biograph mCT-X and mCT-S (and Excel) 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

<u>Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
Biograph mCT-X and mCT-S (Biograph HD)	Siemens Medical Solutions USA, Inc	K101550

Device Description:

The Biograph mCT 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:

- Improvements to Radiation Dose Monitoring
- Radiation Dose Reduction Initiatives
- Image Quality improvements
- Workflow Enhancements

Safety and Effectiveness:

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 14971:2007 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.

Indications for 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.

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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

DEC 17 2011

Re: K113448

Trade/Device Name: Biograph mCT Family – mCT.X, mCT.S
(Including mCT Excel)

Regulation Number: 21 CFR 892.1200

Regulation Name: Emission computed tomography system

Regulatory Class: II

Product Code: KPS & JAK

Dated: November 18, 2011

Received: November 21, 2011

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

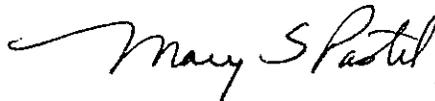
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/cdrh/industry/support/index.html>.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K 113448

Device Name: Biograph mCT Family - mCT-X , mCT-S (including mCT Excel)

Indications for 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K 113448

Page 1 of __