K060631

MAR 1 7 2006

510(k) Summary

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter:	Alaine Medio, RAC
Telephone Number:	(865)218-2703
Fax Number:	(865)218-3019
Date of Submission:	2/10/06

Identification of the product

Device Proprietary Name:	Biograph 64 and Biograph 40
Common Name:	Combination Positron Emission Tomography (PET) and 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

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
Biograph 6	Siemens Medical Systems USA Inc.	K060060
LSO PET/CT HiRez Series	CTI PET Systems (now Siemens Medical Solutions USA Inc.)	K050509
Somatom Project P30F	Siemens Medical Systems USA Inc.	K040665

Device Description:

The Biograph 64 and Biograph 40 are combined Positron Emission Tomography and X-Ray Computed Tomography scanners. These systems are designed for whole-body oncology, neurology and cardiology examinations. The Biograph systems provide registration and fusion of high-resolution metabolic and anatomic information from the two major components of each system, the Siemens LSO HiRez PET scanner and the Siemens Somatom Sensation 64 or 40 CT.

The combined PET/CT scanner is intended for use as a clinical, whole-body machine with high-end spiral CT and PET performance. The CT component provides attenuation correction for PET studies as well as precise anatomical reference through fused PET and CT images. In addition, the PET / CT system maintains independent functionality of the PET and CT scanning systems, allowing for most standard stand-alone CT and PET clinical diagnostic protocols to be available as well.

The Biograph 64 and Biograph 40 systems which are the subject of this application are substantially equivalent to the commercially available Biograph 6 PET/CT system (K060060) and the Siemens Somatom Project P30F CT system (K040665).

Indications for Use:

The Siemens PET/CT scanners are combined Positron Emission Tomography (PET) and X-Ray Computed Tomography (CT) scanners. The Biograph 64 and 40 are intended to be utilized by appropriately trained health care professionals to:

- Image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and
- Produce cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plan taken at different angles or spiral planes taken at different angles.

The Biograph 64 and 40 PET/CTs provide registration and fusion of high-resolution metabolic and anatomic information. The PET component utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for fused PET and CT images. Additionally, the system maintains independent functionality of the PET and CT devices, allowing for single modality CT and / or PET diagnostic imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Siemens Medical Solutions USA, Inc.
% Mr. Daniel Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

Re: K060631
Trade/Device Name: Biograph 64 and Biograph 40
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: KPS and JAK
Dated: March 8, 2006
Received: March 9, 2006

Dear Mr. Lehtonen:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060631

Device Name: Biograph 64 and Biograph 40

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Prescription Use X OR Over the Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060631