K083327

510(K) SUMMARY

AS REQUIRED BY 21 CFR PART 807.87(H)

MAY 18 2009

Identification of the Submitter

Submitter:	Gunhild Paulsen
Telephone Number:	847-304-7516
Fax Number:	847-304-6023
Date of Submission:	10-31-2008

Identification of the product

Device Proprietary Name:	*syngo*Circulation DynamicPET
Common Name:	Picture archiving and communications system
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
ImagenMD™ with ImagenQ ™	Cardiovascular Imaging Technologies	K080770
Syngo® Circulation	Siemens AG Medical Solutions	K063762, K052029

Device Description:

Siemens *syngo*Circulation DynamicPET is a software product intended for visualization, assessment and quantification of medical images. The application supports dynamic Rubidium – PET and Ammonia – PET images.

The application provides visualization and measurement tools, for qualitative and quantitative visualization and assessment of the input data. It provides automatic and manual tools to orient and segment the myocardium. The software calculates measures of myocardial perfusion over time, and provides tools for the Clinician to assess these results. The user may save the results.

The application is intended for use by trained professionals. The Clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual assessment of the myocardial perfusion PET images. The quantitative assessment is to be used in conjunction with traditional visual assessment of myocardial perfusion PET images for the assessment of coronary artery disease.

Safety and Effectiveness:

Risk Management is ensured via a risk analysis in compliance with IEC/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 considers that the proposed device does not introduce new safety concerns, and is substantially the same in indications for use, design, materials, energy sources and technology as the predicate devices. Siemens believes that the *syngo*Circulation DynamicPET software application is substantially equivalent to the predicate devices.

Indications for Use:

Siemens *syngo*Circulation DynamicPET is a software product intended for visualization, assessment and quantification of PET images.

The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion PET images.

The product is intended for use by trained professionals. The Clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual comparison of the information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Mr. Gunhild Paulson
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
2501 N. Barrington Road
HOFFMAN ESTATES IL 60192

Re: K083327
Trade/Device Name: *syngo*Circulation DynamicPET
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 17, 2009
Received: April 21, 2009

Dear Mr. Paulson:

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 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.

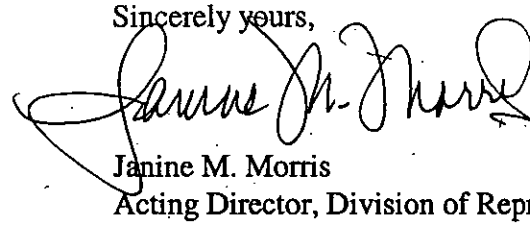
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting 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): K083327

Device Name: *syngo*Circulation DynamicPET

Indications for Use:

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The product is intended for use by trained professionals. The Clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual comparison of the information.

Prescription Use____✓__ 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083327