510(k) - Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	***syngo® Volume Perfusion-CT Body***
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 Erlangen, Germany

4. Contact Person:

Mr. Ralf Hofmann
Regulatory Affairs Specialist
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-8170
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5. Date of Preparation of Summary: Jun. 19th 2009

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

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 hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Substantial Equivalence:

The ***syngo*® Volume Perfusion-CT Body** software package with extended functionality that is addressed in this premarket notification, is substantially equivalent to the following commercially available software packages

Manufacturer	Product	510(k)	Clearance date
1. Siemens AG	syngo Volume Perfusion CT Body	K073373	Dec 18, 2007
2. Siemens AG	syngo Volume Perfusion CT Neuro	K073238	Jan 03, 2008

8. Device Description and Intended Use:

syngo® Volume Perfusion-CT Body software package with extended functionality is a post-processing software package, which runs on an Intel-based PC platform designed to post-process images acquired with SOMATOM CT scanners, which meet certain minimal requirements (i.e. Siemens Definition, Sensation 64, ...). It is a package containing evaluation software that supports the evaluation of Dynamic CT data gathered after the injection of a compact bolus of contrast media, where the contrast media acts as a pure intravascular tracer.

The Siemens syngo Volume Perfusion–CT Body software package with extended functionality has been designed to evaluate perfusion of organs and tumors.

The software can calculate blood flow, blood volume, mean transit time and permeability from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media.

The package also allows the separate calculation of the arterial and portal venous component of hepatic perfusion. It supports evaluation of regions of interest and the visual inspection of time density curves.

A potential application is the characterization of tumors by analysing the differences of perfusion parameters to normal tissue. Determination of the change of perfusion parameters during the course of treatment may be helpful in therapy monitoring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2009

Siemens AG Medical Solutions
% Mr. Stefan Preiss
TÜV SÜD America
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K092013
Trade/Device Name: syngo® Volume Perfusion-CT Body
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 3, 2009
Received: July 6, 2009

Dear Mr. Preiss:

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 (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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/cdrh/mdr/ 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 (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

SIEMENS

Section 2

Indication for use

510(k) Number (if known): K092013

Device Name: **syngo® Volume Perfusion-CT Body**

The Siemens syngo Volume Perfusion–CT Body software package with extended functionality has been designed to evaluate perfusion of organs and tumors.

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The package also allows the separate calculation of the arterial and portal venous component of hepatic perfusion. It supports evaluation of regions of interest and the visual inspection of time density curves.

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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 OF NEEDED)

Concurrence of ~~CDRH~~, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092013