APR - 1 2009

Attachment 8

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® Dual Energy with extended functionality***
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:

Mrs. Corrine McLeod

5. Date of Preparation of Summary: September 10th 2007

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® Dual Energy* software package that is addressed in this premarket notification, is substantially equivalent to the following commercially available Siemens Medical Systems devices :

Manufacturer	Product	510(k)	Clearance date
1. Siemens	syngo Dual Energy	K073003	02/07/2008
2. Siemens	syngo Oncology	K071310	06/08/2007
3. Siemens	SOMATOM DR I	K837107	03/09/1983

8. Device Description and Intended Use:

Device Name: ***syngo® Dual Energy with extended functionality***

Syngo® Dual Energy is designed to operate with Siemens Dual Source CT scanners. CT images taken at the same time, using two different kV levels, of the same anatomical region of a patient are used. Depending on the region of interest, contrast agents may be used. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. The images are combined to visualize and analyze information about anatomical and pathological structures.

The functionality of the *syngo® Dual Energy* applications are as follows:

- Lung Nodules
- Xenon (Lung Ventilation)
- Monoenergetic
- Brain Haemorrhage
- Gout Evaluation
- Lung Vessels
- Heart PBV
- Dual Energy Bone Removal
- Cartilage, Tendon, Ligament
- Lung Perfusion
- Liver
- Hard Plaques in Vessels
- Kidney Stones

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

Ms. Corrine McLeod
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
Corporate Headquarters
51 Valley Stream Parkway
MALVERN PA 19355

Re: K083524
Trade/Device Name: *syngo*® Dual Energy with extended functionality
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 4, 2009
Received: March 16, 2009

Dear Ms. McLeod:

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 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 os 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.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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/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

Indication for use

510(k) Number: **K083524**

Device Name: ***syngo® Dual Energy with extended functionality***

Syngo® Dual Energy is designed to operate with Siemens Dual Source CT scanners. CT images taken at the same time, using two different kV levels, of the same anatomical region of a patient are used. Depending on the region of interest, contrast agents may be used. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. The images are combined to visualize and analyze information about anatomical and pathological structures.

The functionality of the *syngo® Dual Energy* applications are as follows:

- Lung Nodules
- Xenon (Lung Ventilation)
- Monoenergetic
- Brain Haemorrhage
- Gout Evaluation
- Lung Vessels
- Heart PBV
- Dual Energy Bone Removal
- Cartilage, Tendon, Ligament
- Lung Perfusion
- Liver
- Hard Plaques in Vessels
- Kidney Stones

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

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

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

Page ___ of ___

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083524