K081022

JUN - 2 2008

510(K) SUMMARY

FOR

SOMATOM Definition AS/ AS+

Submitted by:

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway

Malvern, PA 19355

September 4, 2007

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.

1. Contact Person:

Mrs. Corrine McLeod
Technical Specialist, Regulatory Affairs Submissions

Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E-50
Malvern, PA 19355-1406
Phone:(601) 448-1772 Fax: (610) 448-1778

2. Device Name and Classification

Product Name:	SOMATOM Project P46
Propriety Trade Name:	SOMATOM Definition AS/ AS+
Classification Name:	Computed Tomography X- ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

3. Substantial Equivalence:

Siemens SOMATOM Definition AS/ AS+ Computed Tomography X-ray systems, configured with software version SOMARIS/7 is substantially equivalent to the following medical device in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens SOMATOM Sensation 64	K040665	04/02/2004
Toshiba Aquilion 64	K063189	11/03/2006

4. Device Description:

The Siemens SOMATOM Definition AS/ AS$^+$ is a Computed Tomography X- ray Systems, which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The SOMATOM Definition AS/AS+ system produces CT images in DICOM format, which can be used by postprocessing applications commercially distributed by Siemens and other vendors.

The computer system delivered with the CT scanner is able to run such post processing applications optionally.

5. Indications for Use:

The SOMATOM Definition AS/ AS$^+$ is intended to produce 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.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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 during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2008

Ms. Corrine McLeod
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E-50
MALVERN PA 19355-1406

Re: K081022
Trade/Device Name: Somatom Definition AS/AS^{+}
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 9, 2008
Received: April 10, 2008

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 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 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.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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (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 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,

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

510(k) Number (if known): _____

Device Name: *Somatom Definition AS/ AS+*

Indications for Use:

The Siemens SOMATOM Definition AS/ AS+ (Project P46) systems are intended to produce 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.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

Prescription Use ____X___ AND/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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081022