K042328

SEP 1 4 2004

510(K) SUMMARY

FOR

SOMATOM PROJECT P15

Submitted by:
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway
Malvern, PA 19355

August 27, 2004

Summary of Safety and Effectiveness

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

Device Name and Classification:

Product Name:	SOMATOM Project P15
Proprietary Trade Name:	SOMATOM Spirit
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK
Establishment Registration Number:	2240869
Performance Standards:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Address:	Siemens Shanghai Medical Equipment Ltd. No.278, Jin Hu Rd. 201206, Shanghai, PRC
Contact Person:	Ms. Nealie Hartman Technical Specialist, Regulatory Affairs Submissions Siemens Medical Solutions, Inc. USA 51 Valley Stream Parkway E-50 Malvern, PA 19355 Phone:(601) 448-1769; Fax: (601) 448-1787

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description:
The Siemens SOMATOM Spirit is a whole body X-ray computed tomography scanners, 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.

Indication for Use:

The SOMATOM Spirit 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 angels 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.)

Technological Characteristics:
The SOMATOM Spirit systems are whole body X-ray computed tomography scanners, which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system is based on the existing SOMATOM Emotion Duo system (for further details see chapter 2). The system will operate with SOMARIS/5.5 software.

General Safety and Effectiveness Concerns:
All components of the SOMATOM Spirit subject to the Federal Diagnostic Equipment Performance Standard and applicable regulations of 21CFR § 1020.30 and § 1020.33 are certified to meet those requirements; and an initial report as per 21 CFR § 1002.10 will be filed with the Center for Devices and Radiological Health (CDRH). To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice. The SOMATOM is designed to meet the ELECTRICAL AND MECHANICAL SAFETY STANDARD IEC 60601-1 and UL 2601 X-RAY EQUIPMENT STANDARD FOR SAFETY.

Substantial Equivalence:
The SOMATOM Spirit systems operating with SOMARIS/5.5 software are substantially equivalent to the following systems:

Product Name	510(k)	Clearance Date
Siemens Emotion Duo	K003014	10/12/00
General Electric's HiSpeed NX/i	K991716	06/18/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2004

Ms. Nealie Hartman
Technical Specialist,
Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E-50
MALVERN PA 19355

Re: K042328
Trade/Device Name: SOMATOM Spirit
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: August 27, 2004
Received: August 27, 2004

Dear Ms. Hartman:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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): K042328

Device Name: SOMATOM Spirit

Indication for use:

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

(Please do not write below this line - continue on another page if needed)

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

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR §801.109)

David G. Hoyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042328