K991764

AUG 17 1999

Attachment 1

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:	SOMATOM Project 10 Computed Tomography X-ray Systems
Classification Name:	§ 892.1750: Computed tomography X-ray system
Propriety Trade Name:	SOMATOM Star / SOMATOM Sprinter
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Registration Number:	2240869
Address:	Siemens Medical Systems, Inc. 186 Wood Avenue South Iselin, N.J. 08830
Contact Person:	Kathleen M. Rutherford Manager, Regulatory Submissions (732) 321-4779

Date of Summary Preparation: 5/20/99

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description:
The Siemens SOMATOM Project 10 systems are 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.

Intended Use:

The SOMATOM P10 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 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 Project 10 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 systems are based on the existing SOMATOM Plus 4 system (for further details see chapter 2). The system will operate with SOMARIS/4.5 software.

General Safety and Effectiveness Concerns:
All components of the SOMATOM Project 10 systems 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 601-1 and UL 187 X-RAY EQUIPMENT STANDARD FOR SAFETY.

Substantial Equivalence:
The SOMATOM Project 10 systems operating with SOMARIS/4.5 software are substantially equivalent to the Siemens SOMATOM Plus 4 and General Electrics Hispeed (DX/i and LX/i) systems in commercial distribution.

Kathleen Rutherford
Manager, Regulatory Submissions

5/21/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 1999

Alicia Juergensen
Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

RE: K991764
Somatom Project 10-CT Scanners
Dated: May 20, 1999
Received: May 24, 1999
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Ms. Juergensen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indication for use

510(k) Number (if known): K991764

Device Name: SOMATOM Project 10 systems

Indication for use:

The SOMATOM Project 10 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 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.)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991764

Prescription Use X
(Per 21 CFR 801.109)