

SEP 30 1998

## Attachment 1

K982349

## 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:****Trade Name:** Somatom Plus 4 with Volume Zoom package**Common Name:** CT Scanner**Classification Name:** § 892.1750:  
Computed tomography X-ray system**Classification:** Class II**Performance Standard:** 21 CFR Subchapter J,  
Federal Diagnostic X-ray Equipment Standard**Establishment:****Address:** Siemens Medical Systems, Inc.  
186 Wood Avenue South  
Iselin, N.J. 08830**Registration Number:** 2240869**Contact Person:**Kathleen M. Rutherford  
Manager, Regulatory Submissions  
(732) 321-4779**Date of Summary Preparation:**

6/29/98

## II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

### Device Description:

The Siemens Somatom Plus 4 with Volume Zoom package is a whole body X-ray computed tomography scanner 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 Plus 4 with Volume Zoom package is used for whole body X-ray computed imaging.

### Technological Characteristics:

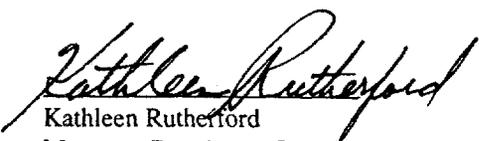
The SOMATOM Plus 4 with Volume Zoom package is a whole body X-ray computed tomography scanner, which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system is based on the existing SOMATOM Plus 4 system (for further details see section 3). The Volume Zoom functionality will be marketed as an optional package for the existing SOMATOM Plus 4 system and will also be offered as an upgrade to already installed systems. The system will operate with SOMARIS/5 software.

### General Safety and Effectiveness Concerns:

All components of the Somatom Plus 4 with Volume Zoom package subject to the Federal Diagnostic Equipment Performance Standard and applicable regulations of 21CFR § 1020.30 and § 1020.33 will 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). The SOMATOM is designed to meet the ELECTRICAL AND MECHANICAL SAFETY STANDARD IEC 601-1, +A1:1991, +A2:1995, and IEC 60601-1-2.

### Substantial Equivalence:

The Somatom Plus 4 with Volume Zoom package operating with SOMARIS/5 software is substantially equivalent to the Siemens SOMATOM Plus 4, GE CT/I, Elscint Twin Flash and SOMATOM Plus 4 Power systems in commercial distribution.

  
Kathleen Rutherford  
Manager, Regulatory Submissions

7/1/98  
Date



SEP 30 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Alicia Juergensen  
Technical Specialist  
Siemens Medical Systems, Inc.  
186 Wood Ave. South  
Iselin, NJ 08830Re: K982349  
Somatom Plus 4 with Volume Zoom CT Scanners  
Dated: June 29, 1998  
Received: July 6, 1998  
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 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,

Lillian Yin, Ph.D.  
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

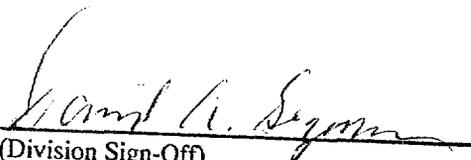
510(k) Number (if known): K982349

Device Name: Somatom Plus 4 with Volume Zoom package

#### Indication for use:

The Somatom Plus 4 with Volume Zoom package 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.)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K982349

Prescription Use   
(Per 21 CFR 801.109)