510(K) SUMMARY K042229
FOR
SIEMENS RADIATION TREATMENT PLANNING (RTP) PACKAGE

Submitted by:

Siemens Medical Solutions, Inc.
51Valley Stream Parkway
Malvern, PA 19355

August 17, 2004

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:**

Ms. Nealie Hartman
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E50
Malvern, PA 19355
Phone: (610) 448-1769
Fax: (610) 448-1787
Email: nealie.hartman@siemens.com

2. **Device Name and Classification**

Product Name:	SOMATOM Radiation Treatment Planning (RTP) package
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

3. **Importer/Distributor Establishment:**

Registration Number: 2240869
Siemens Medical Solutions, Inc. USA
51 Valley Stream Pkwy
Malvern, PA 19355

K042229

4. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany

5. Substantial Equivalence

The Radiation Treatment Planning (RTP) Package, addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens SOMATOM Emotion 6 (P10)	K023687	11/22/02

6. Device Description

A dedicated RTP package for the SOMATOM Emotion CT Systems includes both hardware and software components and further improves the geometric accuracy of anatomical data. The RTP package will provide the following:

- **Improved gantry tilt accuracy:**
  The gantry tilt angle is displayed in 0.5 degree increments.
- **Reduced table top deflection:**
  The tabletop deflection is reduced, by replacing the CT table, allowing for more accurate patient positioning.
- **Externally adjustable gantry laserlights:**
  A position adjustment of the gantry laserlights is possible without opening the gantry thus allowing easier installation and synchronization with room RTP lasers.
- **Increased x-ray tube positioning accuracy:**
  The accuracy of x-ray tube positioning for Topogram scans is improved to a range of ± 2 degrees.
- **Simplified horizontal positioning of the table:**
  During an examination, a table feed position can be stored enabling fast and easy repositioning of a patient back to the previous table position (tolerance of ± 1mm).
- **Optimized field coverage using extended Field of View (FOV):**
  The FOV is extended to 70 cm for maximum anatomical visualization and improved RTP positioning.

K042229

7. Indications for Use

The use of standard CT scanners in Radiation Treatment Planning environments requires a higher geometric accuracy of anatomical data. For the Siemens SOMATOM Emotion CTs and all further CT devices a dedicated RTP package (including both hardware and software components) will be offered and provides the following features:

- improved gantry tilt accuracy
- reduced table top deflection
- externally adjustable gantry laserlights
- increased tube positioning accuracy
- simplified horizontal positioning of the table
- optimized field coverage using extended Field of View

Radiation Treatment Planning (RTP) Package will be used to prepare geometric and anatomical data, which may assist the physician with proposed external beam radiotherapy treatment planning.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2004

Ms. Nealie Hartman
Technical Specialist
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E50
MALVERN PA 19355

Re: K042229
Trade/Device Name: SOMATOM Radiation Treatment Planning (RTP) Package
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: August 17, 2004
Received: August 17, 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): K042229
Device Name: **Radiation Treatment Planning (RTP) package**

The use of standard CT scanners in Radiation Treatment Planning environments requires a higher geometric accuracy of anatomical data.

For the Siemens SOMATOM Emotion CT systems, a dedicated RTP package (including both hardware and software components) will be offered and provides the following features:

- improved gantry tilt accuracy
- reduced table top deflection
- externally adjustable gantry laserlights
- increased tube positioning accuracy
- simplified horizontal positioning of the table
- optimized field coverage using extended Field of View

Radiation Treatment Planning (RTP) Package will be used to prepare geometric and anatomical data, which may assist the physician with proposed external beam radiotherapy treatment planning.

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

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

Prescription Use
(Per 21 CFR §801.109)

OR Over-The-Counter Use

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042229