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K032475

**510(k) SUMMARY  
FOR THE  
SLIDING GANTRY OPTION FOR CT DEVICES**

Submitted by:

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

July XX, 2003

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  
51 Valley Stream Parkway  
Malvern, PA 19355  
Phone: (610) 448-1769  
Fax: (610) 448-1787

**2. Device Name and Classification**

Product Name: Sliding Gantry Option for CT Devices  
Common Name: Computed Tomography X-ray system  
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.  
51 Valley Stream Pkwy  
Malvern, PA 19355

**4. Manufacturing Facility:**

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

K032475

**5. Substantial Equivalence**

The *Sliding Gantry Option* for CT Devices, addressed in this premarket notification, is substantially equivalent to the following commercially available systems

<i>Predicate Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>
Siemens Angio-CT MIYABI	K990491	04/05/99
Siemens Plus 4 with Sliding Gantry Option	K991600	06/09/99

**6. Device Description**

The *Sliding Gantry* option is designed to allow whole body x-ray computed tomography scanning on a single patient that can be performed on different types of patient tables in different environments. The *Sliding Gantry Option* integrates the function of precise scan control driven horizontal movement, which is usually a function of the dedicated CT-table, into the CT gantry itself. The original CT gantry is mounted on a rail system and a scan control system moves the gantry relative to the table, instead of moving the table relative to the gantry.

**7. Intended Use**

The CT device with *Sliding Gantry Option* 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 movement of the *Sliding Gantry*).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 10 2003

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

Re: K032475  
Trade/Device Name: SOMATOM Computed Tomography  
X-ray Systems with Sliding Gantry Option  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography  
x-ray system  
Regulatory Class: II  
Product Code: 90 JAK  
Dated: August 8, 2003  
Received: August 16, 2003

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.

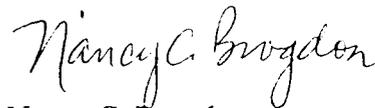
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

SECTION 2

INDICATIONS FOR USE

510(k) Number (if known): K032475  
Device Name: *Sliding Gantry Option* for Siemens CT systems

The CT device with *Sliding Gantry Option* 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 movement of the *Sliding Gantry*).

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

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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 K032475