SIEMENS

MAR 1 8 2005

K050422

Tab 1
510(k) Summary

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems Group
4040 Nelson Avenue
Concord, CA 94520

Contact: Ken Nehmer
Senior Manager of Regulatory Affairs

Phone: (925)602-8011
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Proprietary Name: 550 TxT Treatment Table

Common Name: Couch, Radiation Therapy, Powered

Classification: 892.5770

Product Code: JAI

Substantial Equivalence Claimed To:

ZXT Treatment Table	K910971	cleared on May 3, 1991

Description:

The 550 TxT Treatment Table is a powered radiation therapy patient support assembly that is substantially equivalent in functionality as the previously cleared ZXT Treatment Table (K910971). Refer to Tab 8 and Tab 9 for detailed information regarding the 550 TxT Treatment Table requirements and specifications.

The 550 TxT Treatment Table is to be used in conjunction with Siemens linear accelerator systems. The table is supported by a single column and features several functions including isocentric rotation, column rotation, longitudinal, lateral, and vertical motions.

The 550 TxT Treatment Table design improves the quality of treatment delivery by providing greater patient positioning accuracy and higher load capacity as compared to the ZXT Treatment Table. The new ergonomic interface enables users to control the movements of the treatment table either manually with the free float function or smoothly by using the motorized movements.

Intended Use:

The 550 TxT Treatment Table is to be used as an integral part of the Siemens linear accelerator systems to position the patient accurately according to the treatment plan for various radiation therapy treatment techniques. The table can be controlled either within the treatment room via the table interface or remotely from the linear accelerator control console.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2005

Mr. Ken Nehmer
Senior Manager of Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Oncology Care Systems Group
4040 Nelson Avenue
CONCORD CA 94520

Re: K050422
Trade/Device Name: 550 TxT Treatment Table
Regulation Number: 21 CFR §892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: JAI
Dated: February 16, 2005
Received: February 18, 2005

Dear Ms. Dunbar:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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

510(k) Number (if known): K050422

Device Name: 550 TxT Treatment Table

Indications for Use:

The 550 TxT Treatment Table is to be used as an integral part of the Siemens linear accelerator systems to position the patient accurately according to the treatment plan for various radiation therapy treatment techniques. The table can be controlled either within the treatment room via the table interface or remotely from the linear accelerator control console.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050422

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)