K112446

OCT - 7 2011

TomoTherapy.

Section 2 510(k) Summary

Applicant:

TomoTherapy, Inc.
1209 Deming Way
Madison, WI 53717-1954
Phone: 608.824.2800
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Contact: Gregory G. Bange
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Date Prepared: August 19, 2011

Device Identification:

Device Name:	TomoTherapy Treatment System
Trade Names	Hi-Art® and TomoHD™
Common Name:	Radiation Therapy System
Classification:	System, Planning, Radiation Therapy Treatment
Product Code:	MUJ, IYE
Regulation Number:	21 CFR 892.5050
Regulation Description:	Medical charged particle radiation therapy system

Predicate Device:

TomoTherapy Hi-Art System (modified) K082005

Description:

The TomoTherapy Treatment System is a radiation therapy system that integrates planning, dose calculation, megavoltage CT imaging for IGRT functionality, and helical (rotational) and fixed beam (non-rotational) radiation therapy treatment capabilities into a single comprehensive system.

The TomoTherapy Treatment System is a prescription device. It delivers radiation in accordance with a physician approved plan. The device does not diagnose disease, recommend treatment regimens, or quantify treatment effectiveness. The megavoltage CT imaging functionality is not intended for diagnostic use.

Intended Use:

The TomoTherapy Treatment System is intended to be used as an integrated system for the planning and precise delivery of radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue. The megavoltage x-ray radiation is delivered in a rotational, non-rotational, modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) format in accordance with the physician approved plan.

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Technological Characteristics:

The technological characteristics of the TomoTherapy Treatment System are substantially equivalent to the predicate. The TomoTherapy Treatment System consists of the same primary subassemblies, is comparable in key safety and effectiveness features, utilizes substantially similar design, construction, materials, energies, and it has an intended use that is identical to that of the predicate device. It is important to note that while this addition addresses consistency of dose output, the operation of the independent dose monitoring/interlock system is completely unchanged. Therefore the dose monitoring/interlocks operation is identical to pre-existing functionality and performance limits.

Enhancements to the radiation delivery system improve the consistency of the dose rate of the TomoTherapy Treatment System in comparison to the predicate device. This does not alter the performance claims for the product. These technological enhancements do not raise new type of safety or effectiveness questions.

Performance Data:

The TomoTherapy Treatment System was tested and demonstrated to conform to the requirements of applicable recognized consensus standards for medical devices. Results of verification and validation tests, including extensive tests of imaging and radiation delivery functionality, confirm the TomoTherapy Treatment System performance is within design specifications. No clinical tests were required to establish substantial equivalence. These performance data demonstrate the TomoTherapy Treatment System is as safe, as effective, and performs as well as the predicate device.

Summary:

The TomoTherapy Treatment System is substantially equivalent to the predicate device. The intended use, major technological characteristics, and principles of operation of the TomoTherapy Treatment System are identical to those of the predicate device. Minor technological differences do not raise new types of safety or effectiveness questions. Performance data demonstrate the TomoTherapy Treatment System is as safe, as effective, and performs as well as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT - 7 2011

Mr. Greg Bange
Manager of Regulatory Submissions and Standards
TomoTherapy, Inc.
1240 Deming Way
MADISON WI 53717-1954

Re: K112446
Trade/Device Name: TomoTherpy Treatment System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: August 19, 2011
Received: August 24, 2011

Dear Mr. Bange:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 1 Indications for Use Form

510(k) Number (if known): K112446

Device Name: TomoTherapy Treatment System

Indications for use:

The TomoTherapy Treatment System is intended to be used as an integrated system for the planning and precise delivery of radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue. The megavoltage x-ray radiation is delivered in a rotational, non-rotational, modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) format in accordance with the physician prescribed and approved plan.

Prescription Use X AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 subpart D) (Per 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)

Division Sign-Off
Office of In-Vitro Diagnostic Device
Evaluation and Safety

510(k) K112446