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TomoTherapy INCORPORATED

1.4 Safety and Effectiveness Summary

GENERAL INFORMATION

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Contact Person:	Kenneth D. Buroker TomoTherapy Incorporated 1240 Deming Way Madison, WI 53717-1954
Phone:	(608) 824-2811
Fax:	(608) 824-2991
Date:	March 31, 2006
Device Trade Name:	HI-ART System (modified)
Common Name:	Radiation Therapy System
Classification Name:	Medical Charged Particle Radiation Therapy System
Predicate Device:	TomoTherapy Hi-Art System K042739

INTENDED USE

The TomoTherapy HI-ART System® is intended to be used as an integrated system for the planning and delivery of intensity modulated radiation therapy (IMRT). The HI-ART System provides precise delivery of radiation to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue.

The HI-ART System's planning station or operator station is intended to be used by the physician/oncologist to prescribe a radiation therapy plan for a particular patient. The HI-ART System then calculates the treatment plan which the physician reviews and approves.

The HI-ART system's operator station and status console is then intended to be used by the therapist to select and implement the patient's treatment plan. The treatment process will begin by performing a TomoImage™ (MVCT) scan (a CT using the onboard linear accelerator as the radiation source). This TomoImage (MVCT) will confirm that the patient's position is correct for the radiation therapy as well as assist in patient re-positioning when necessary. The TomoImage (MVCT image) is not for diagnostic use.

When patient positioning is complete, the HI-ART System is then intended to be used by the therapist to treat the patient using the selected treatment plan. The HI-ART System delivers the radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery treatment in accordance with the physician approved plan delivered in a helical tomographic pattern.

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DESCRIPTION

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The TomoTherapy HI-ART System is a radiation therapy system that integrates planning, dose calculation, megavoltage CT scanning, and helical radiation therapy treatment capabilities into a single comprehensive IMRT system.

The HI-ART System's planning station or operator station is used by the physician to prescribe and enter the radiation therapy plan. A diagnostic CT image imported via a DICOM protocol from another diagnostic CT device or a TomoImage (MVCT) scan is used as the basis for the plan. The regions of interest, regions to avoid, and other prescribing information are entered in a manner that is similar to other commercially available planning systems.

The HI-ART System utilizes a 6 MV linear accelerator as the radiation source. The linear accelerator along with the primary collimator, multi-leaf collimator (MLC), detector, various control devices and power supplies are mounted on a rotating gantry, much like a CT gantry. During treatment or imaging, the patient is positioned on the couch support, and the couch moves axially through the bore of the gantry, and the radiation is delivered in a helical pattern.

The primary collimator and the MLC control the beam dimensions during radiation delivery so that the range of collimated beam size can vary from 0 to 400 mm wide by 5 to 50 mm at the isocenter. The MLC is constructed of 64 tungsten leaves that open and close as determined by the radiation therapy plan. The intensity of the radiation beam is proportional to the length of time that a particular leaf is open. The opening and closing of various leaves as the radiation is delivered in this helical pattern allows for an IMRT plan to be delivered with precise control. The result is a highly conformal dose to the region of interest with low doses to surrounding healthy tissue.

Because the HI-ART System is operating in a helical mode similar to CT systems, it inherently has the ability to obtain a CT image. The system utilizes the linear accelerator to obtain a megavoltage (MVCT) scan of the region of interest prior to the delivery of radiation therapy. This MVCT image is then used to ascertain that the patient is correctly positioned prior to treatment. The radiation dose to the patient from an MVCT scan is comparable to diagnostic CT or portal imaging.

SAFETY CONSIDERATIONS

The HI-ART System has several characteristics that promote its safety – no beam blocks are used that can fall off onto the patient; the rotating gantry is covered so that the patient cannot contact moving gantry parts; the linear accelerator operates in photon mode only so inadvertent electron exposure is virtually eliminated; MVCT allows for reliable patient positioning.

Also, the HI-ART System consists of components similar to those already commercially marketed, including the 6 MV linear accelerator, rotating gantry, patient couch and CT imaging devices.

STANDARDS COMPLIANCE

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The HI-ART System is designed to comply with relevant sections of the IEC 60601-1, IEC 60601-2-1, IEC 60601-1-2, IEC 60601-1-4 safety standards and EN ISO 14971:2000.

VALIDATION

The HI-ART System was extensively validated for system functionality, including planning, imaging, delivery, database management, DICOM communications, etc. Test tools utilized in this testing included IMRT phantoms, ion chambers and other test phantoms.

CONCLUSION

Validation and verification testing of the HI-ART System demonstrates the device is safe and effective for its intended use. The HI-ART System with modifications is substantially equivalent to the HI-ART system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Mr. Kenneth D. Buroker
Vice President of Regulatory Affairs
TomoTherapy, Inc.
1240 Deming Way
MADISON WI 53717-1954

Re: K060912
Trade/Device Name: TomoTherapy HI-ART System® (modified)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE and MUJ
Dated: March 31, 2006
Received: April 3, 2006

Dear Mr. Buroker:

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/industry/support/index.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

1.3 Indications for Use Form

- 510(k) Number (if known) K060912
- Device Name: **TomoTherapy HI-ART System® (modified)**
- Indications for use:

The TomoTherapy HI-ART System is intended to be used as an integrated system for the planning and delivery of intensity modulated radiation therapy (IMRT). The HI-ART System provides precise delivery of radiation to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue.

The HI-ART System's planning station or operator station is intended to be used by the physician/oncologist to prescribe a radiation therapy plan for a particular patient. The HI-ART System then calculates the treatment plan which the physician reviews and approves.

The HI-ART system's operator station and status console is then intended to be used by the therapist to select and implement the patient's treatment plan. The treatment process will begin by performing a TomoImage™ (MVCT) scan (a CT using the onboard linear accelerator as the radiation source). This TomoImage (MVCT) will confirm that the patient's position is correct for the radiation therapy as well as assist in patient re-positioning when necessary. The TomoImage (MVCT image) is not for diagnostic use.

When patient positioning is complete, the HI-ART System is then intended to be used by the therapist to treat the patient using the selected treatment plan. The HI-ART System delivers the radiation therapy treatment, stereotactic radiotherapy, or stereotactic radiosurgery in accordance with the physician approved plan delivered in a helical tomographic pattern.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 810.109)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060912