K090893

JUL 15 2009

510(k) Executive Summary

July 8, 2009

1. Submitter's Information

Company Name: LinaTech, LLC

Company Address: 1294 Kifer Road, #705
Sunnyvale, CA 94086

Trade Name: TiGRT TPS

Common Name: Radiation Treatment Planning System

Classification Name: System, Planning, Radiation Therapy Treatment

2. Predicate Device Identification

21 CFR 892.5050

Radiation Treatment Planning System

Product Code: MUJ

Device Class: II

3. Legally Marketed Equivalent Device

WIMRT (K041971)

4. Intended Use and Device Description

TiGRT TPS is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. TiGRT TPS is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray and/or electron energies from 1 to 25MV, as well as Cobalt-60.

The intended use is the same as the predicate device.

5. Technological Characteristics of the Device as to Compared to Predicate Device

Predicate Product Comparison Table:

Characteristic	Current Modified Device TiGRT TPS	Predicate Device WiMRT (K041971)
Operating System	Windows XP Professional Windows Vista	Windows XP Professional
Networking	TCP/IP	TCP/IP
Intended Use	TiGRT TPS is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. TiGRT TPS is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray, electron and/or photon energies from 1 to 25MV, as well as Cobalt-60.	The product WiMRT is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. WiMRT is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray energies from 1 to 25MV, as well as Cobalt-60, and electron energies from 1 to 25 MeV.
Application(Use)	Conformal Planning; Step & Shoot Inverse IMRT Planning Dynamic Sliding Window Inverse IMRT Planning SRS and SRT.	Conformal Planning; Step & Shoot Inverse IMRT Planning Dynamic Sliding Window Inverse IMRT Planning SRS and SRT
Dose Calculation Algorithm	Super-position Convolution	Super-position Convolution
IMRT Optimization Algorithm	Genetic Algorithm for IMRT segmentation, Auto-beam angle selection	Genetic Algorithm for IMRT segmentation, Auto-beam angle selection
DICOM	DICOM 3/RT	DICOM 3/RT

Comparisons Summary

A. Intended Use

TiGRT TPS is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. TiGRT TPS is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray and/or electron energies from 1 to 25MV, as well as Cobalt-60.

The intended use is the same as the predicate device.

B. Technological Characteristics

The predicate device is presently in commercial distribution globally including the United States of America. The TiGRT TPS has the similar technological characteristics and is similar in design, function, and application to the predicate device.

The Technological Characteristics are the same as the predicate devices.

C. Differences

This device is similar in design and construction, and has the same intended use and performance characteristics to the predicate device. It utilizes materials that are already in use in other medical devices. No new issues of safety or effectiveness are introduced by using this device.

D. Argument for Substantial Equivalence to Predicate Devices

The intended use and the technological characteristics of TiGRT TPS are the same as the predicate device and therefore we believe it is Substantially Equivalent to it.

6. Biocompatibility

No new issues of biocompatibility are raised with regard to this device.

7. Summary for Performance Testing

This device is similar in design and construction, and has the same intended use and performance characteristics to the predicate device. It utilizes materials that are already in use in other medical devices. No new issues of safety or effectiveness are introduced by using this device.

Performance Documentation	Concern
Level of Concern of TPS	Major
TiGRT TPS Description	Provided
TiGRT TPS Risk Management	Provided
TiGRT TPS Hazard Analysis Report	Provided
TiGRT TPS Product Requirement Specification	Provided
TiGRT TPS Architecture Design Chart	Provided
TiGRT TPS Software Design Description	Provided
TiGRT TPS PRS/SDD Traceability Matrix	Provided
TiGRT TPS PRS/STT Traceability Matrix	Provided
TiGRT TPS Development Environment Description	Provided
TiGRT TPS Verification and Validation Documents	Provided
TiGRT TPS Revision Level History	Provided
TiGRT TPS Unresolved Anomalies (Bugs or Defects)	Provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

Mr. Jonathan Yao
President
LinaTech, LLC
1294 Kifer Road, Suite 705
SUNNYVALE CA 94086

Re: K090893
Trade/Device Name: TiGRT TPS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: June 18, 2009
Received: June 22, 2009

Dear Mr. Yao:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K090893

Device Name: TiGRT TPS

Indications for Use:

TiGRT TPS is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. TiGRT TPS is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray and/or electron energies from 1 to 25MV, as well as Cobalt-60.

(PLEASE DO NOT WRITE BELLOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

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

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090893