K133191
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Premarket Notification [510(k)] Summary
ProBeam Proton Therapy System

JAN 10 2014

The following information is provided following the format of 21 CFR 807.92.

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way e-110
Palo Alto, CA 94304

Contact Name: Vy Tran
Phone: 650/424.5731
Fax: 650/842.5040
Date: 9 October 2013

Proprietary Name:

ProBeam

Classification Name:

Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: LHN

Common/Usual Name:

Proton Therapy System

Predicate Devices:

1) ProBeam Proton Therapy System (K101294)
2) Varian On-board Imager Device (K042720)

Device Description:

ProBeam Proton therapy system, has been designed by Varian Medical Systems to deliver radiation treatment in accordance with a prescribed treatment plan. The system takes advantage of the characteristics of proton charged particle beam delivery. The major characteristic of proton radiation therapy utilizes the Bragg peak to prevent radiation of normal tissue outside the target volume.

The system consists of 4 major components:
1) Cyclotron required to generate the proton beam (output 250MeV)
2) Beam line to transport beam from the cyclotron to the required treatment room
3) Treatment room where the patient is irradiated as per the prescribed treatment plan
4) Control room to select patient and activate treatment delivery

Statement of Intended Use

ProBeam Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Statement of Indications for Use:

ProBeam Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Technological Characteristics: Refer to the Substantial Equivalence discussion in the table below:

Feature	Predicate Device:	Modified Device:
	ProBeam (K101294) (Note: Also known as PT2 Varian Proton Therapy System)	**ProBeam**
Intended Use	PT2 Varian Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	ProBeam Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
Indications For Use	PT2 Varian Proton Therapy System, provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	ProBeam Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
Proton Accelerator	Isochronous Cyclotron (superconducting type using helium cryogen cooling)	No change
Treatment Particle	Proton	Proton
Cyclotron energy	250 MeV	No change
Proton Energy Selection	90-230 MeV (usable energy range)	70 - 240 MeV (usable energy range)
Energy Selection	Via mechanical degrader system and Energy Selection System based on magnetic deflection	No Change
Beam Transport	Standard beam optical system with quadrupoles and dipole magnets	No Change
Number of beam delivery rooms	1 to 4 treatment rooms with isocentric gantries. No fixed beam treatment stations.	Customer can choose up to 6 beam delivery room modules. The facility would be comprised of a combination of modules including Treatment rooms (either Isocentric gantries or fixed beam) and/or research rooms
Beam angle adjustment	Adjustable via Rotating Isocentric Gantry	Adjustable only in Rotating Isocentric Gantry rooms For fixed beam rooms the beam is provided at a fixed angle
Beam delivery	Beam Spot Scanning in all treatment stations	No change
	Note: The beam spot scanning is defined as the act of moving a charged particle beam of particular properties from one spot to the next over the whole treatment volume and/or changing one or more of the properties of that beam (e.g. Intensity (e.g. # protons/second), position etc.). The charged particle beam stops on each spot until the predefined the proton fluence according to a prescription is reached and moves to the next spot. After one layer of spots is done the depth will be changed by the change of the energy and the next layer of spots will be executed.	Note: The beam spot scanning is defined as the act of moving a charged particle beam of particular properties from one spot to the next over the whole treatment volume and/or changing one or more of the properties of that beam (e.g. Intensity (e.g. # protons/second), position etc.). The charged particle beam stops on each spot until the predefined the proton fluence according to a prescription is reached and moves to the next spot. After one layer of spots is done the depth will be changed by the change of the energy and the next layer of spots will be executed.
Laser positioning system	Included	Included
Beam characteristics: spot shape	4 mm (Sigma) in the specified range(tolerance range: for energies ≤100 MeV, beam spot size + 30% / -20%, for energies> 100 MeV beam spot sizes ± 20%)	4.0 mm +/- 15% (Sigma) for beam energies equal or greater than 140 MeV to 240 MeV. (-0.02 * E / MeV + 6.8) +/- 15 % mm for beam energies E from 70 MeV to less than 140 MeV.
Beam characteristics: field size	Maximum field size is 25cm (x) x 25cm(y)	Maximum field size is 30cm (x) x 40cm(y)

Feature	Predicate Device:	Modified Device:
Maximum deviation of undeflected beam from isocenter	3.0 mm	1.0 mm
Value of energy dose rate at the Nominal Treatment Distance	>1 Gy/l /min	2 Gy/l/min
Patient Positioning	Varian 6-Axis Treatment Table	Forte 6-Axis Robotic Treatment Table (K122413)
Maximum Load	150Kg (330lbs)	273 Kg (550lbs)
Pitch	±3°	No Change
Roll	±3°	No Change
Absolute positioning precision, radius sphere	≤ 0.5 mm	No Change
Patient Position Verification System	Not included	Included
	Varian On-board Imager Device (K042720)	**ProBeam Device Component: kV Imaging**
Target localization technology	Single kV X-ray System	Dual kV X-ray System
2D/3D Match	Not included	Included
X-ray source	Varian G-242	Varian GS-20712
Voltage	40-150kV	40-140kV
Exposure	0.5-630 mAs	0.1-370.1 mAs
Flat panel digital x-ray detector	Varian PaxScan 4030CB	No Change
Detector pixel elements	Amorphous Silicon (a-Si:H) photodiode plus thin film transistor	No Change
Type of digital image produced	digital radiographs or fluoroscopy	digital radiographs
Basis of image comparison	soft tissues, bony anatomy or fiducial markers	No change
Image comparison techniques	Fully automatic using mutual information, semi-automatic, or manual	No change

Summary of Performance Testing:

Testing has been performed at the system and sub-system level and demonstrated ProBeam is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Varian Medical Systems
% Ms. Vy H. Tran
Vice President Corporate Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304-1038

January 10, 2014

Re: K133191
Trade/Device Name: ProBeam Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: October 18, 2013
Received: October 21, 2013

Dear Ms. Tran:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K133191

Device Name: ProBeam Proton Therapy System

Indications for Use:

ProBeam Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) K133191