K100890

510(k) Summary

The information below is provided for the Varian High Energy Linear Accelerator, following the format of 21 CFR 807.92.

1. Submitter:

Varian Medical Systems
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Palo Alto, CA 94304
Contact Name: Vy Tran
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JUL 13 2010

2. Name of the Device: Varian High Energy Linear Accelerator

Trade / Proprietary Names:
Novalis Tx, Trilogy, Trilogy Tx
Clinac iX, Clinac Cx
Clinac 2100C, 2100 C/D, 2300 C/D
Clinac 21 EX, 23 EX
Clinac DHX, DMX

Common or Usual Names:
Novalis Tx, Trilogy, Trilogy Tx
Clinac iX, Clinac Cx
Clinac 2100C, 2100 C/D, 2300 C/D
Clinac 21 EX, 23 EX
Clinac DHX, DMX

Classification Name:
Medical Charged Particle Radiation Therapy System
21 CFR §892.5050
Class II

Product Code: 90 IYE

3. Predicate Device:
Varian Trilogy Radiotherapy System: K081188, K072916

4. Description of the Device:

The Varian High Energy Linear Accelerator models provide various selections among the features, specifications, and accessories that have been most recently cleared as Trilogy Radiotherapy Delivery System (K081188, K072916).

The 8.0 release of the C-Series control software provides additional features, safety improvements, and usability improvements.

All other features of the Varian High Energy Linear Accelerator models remain as cleared by K081188, K072916.

5. Intended Use Statement

The Varian High Energy Linear Accelerator is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

6. Indications for Use Statement

The Varian High Energy Linear Accelerator is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

7. Substantial Equivalence

The Varian High Energy Linear Accelerator submission illustrates substantial equivalence to the predicate device.

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

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

JUL 13 2010

Re: K100890
Trade/Device Name: Varian High Linear Accelerator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 28, 2010
Received: June 1, 2010

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.

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100890

Device Name: Varian High Energy Linear Accelerator

Indications for Use:

The Varian High Energy Linear Accelerator is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100890