K101751

510(k) Summary

The information below is provided for the UNIQUE, following the format of 21 CFR 807.92.

AUG 10 2010

1. Submitter:

Varian Medical Systems
3100 Hansen Way, M/S E110
Palo Alto, CA 94304
Contact Name: Vy Tran
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E-mail: vy.tran@varian.com

2. Name of the Device: UNIQUE
   Trade / Proprietary Names: UNIQUE

   Common or Usual Names: Single Energy Linear Accelerator

   Classification Name: Medical Charged Particle Radiation Therapy System
   21 CFR §892.5050
   Class II
   Product Code: 90 IYE

3. Predicate Device: Varian Trilogy K072916

4. Description of the Device:

   The UNIQUE is a Single Energy Linear Accelerator and includes modifications to the previously cleared Varian Trilogy. The UNIQUE provides additional features, safety improvements, and usability improvements. UNIQUE is supported by the following Varian accessories: RPM Respiratory Gating (063270), PortalVision (K091209), 4D Integrated Treatment Console (K091132), Millennium Multi-Leaf Collimator (K050442).

5. Intended Use Statement

   The UNIQUE 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 UNIQUE 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 UNIQUE is substantially equivalent to the predicate device, the Varian Trilogy.

The functionality of the UNIQUE is equivalent to the functionality of the Varian Trilogy in safety and effectiveness. Varian design control procedures applied to the development of the UNIQUE include requirements reviews, risk analysis, and verification and validation testing. The results of verification and validation activities demonstrate that the acceptance criteria have been met.

Compared with the predicate device, the Varian Trilogy, the basic operation is the same. Operational differences are described in the Instructions for Use for the UNIQUE.

Substantial Equivalence Table

The table below illustrates the substantial equivalence between the UNIQUE and the predicate device, the Varian Trilogy (K072916).

The intended use for both devices is to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Item	Trilogy – K072916	UNIQUE
C-Series Software: improvements for usability and safety, as well as support for additional features	C-Series 7.7	C-Series 8.0
Photon Energy (MV) available	4-25 MV	6 MV
Selectable Number of Photon Beams	Two	One
Dose Rates	50-600 MU/min (1000 SRS rate)	100 – 600 MU/min (No SRS rate)
Maximum standard treatment field size	40cm x 40cm	40cm x 40cm
Electron Treatment	Yes	No
Arc Treatments: Standard and RapidArc where gantry rotation speed and dose rate are varied.	Yes	Yes
Non-arc photon treatment mode programmable MU maximum dose	999 MU	1999 MU
Patient Support surface: Exact Couch	Yes	Yes
Patient support surface: Exact couch pedestal with IGRT couch top for improved MV imaging	No	Yes
Drive mechanism	Direct Drive	Clutch
Treatment Beam generation	Klystron	Magnetron
Support for External System Gating Interface "EXGI" (K072916) – export of beam information to external devices	No	Yes

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
Official Correspondent
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

AUG 10 2010

Re: K101751
Trade/Device Name: UNIQUE
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 18, 2010
Received: June 22, 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.

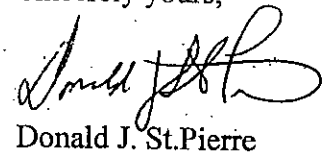
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K101751

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Indications for Use

AUG 1 0 2010

510(k) Number (if known): K101751

Device Name: UNIQUE

Indications for Use:

The UNIQUE 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 K101751