K033343

DEC 2 3 2003

VARIAN
medical systems

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510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the Trilogy Radiotherapy Delivery System

1. Submitter: Varian Medical Systems
   3100 Hansen Way M/S H055
   Palo Alto, CA 94304-1129
   Contact Name: Vy Tran
   Phone: (650) 424-5731
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   Email: vy.tran@varian.com
   Date summary was prepared: October 16, 2003

2. Name of the Device: Trilogy Radiotherapy Delivery System
   Trade/Proprietary Name: Trilogy Radiotherapy Delivery System
   Common or Usual Name: Trilogy system
   Classification Name: Medical Charged Particle Radiation Therapy System
   21 CFR §892.5050
   Class II
   Product Code: 90 IYE

3. Predicate Devices to claim substantial equivalence:
   a. Varian Medical Systems' Clinac 2300 C/D, K913119
   b. Brainlab Novalis Shaped Beam Surgery System, K002509

4. Description of the Device: The modified 2300C/D, which will now be called the Trilogy™ Radiotherapy Delivery System, will include stereotactic functionality and remote couch motions as new features. The Trilogy™ Radiotherapy Delivery System is an image-guided, dual-energy, high-dose medical linear accelerator optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy and stereotactic applications. The stereotactic applications include single-session radiosurgery, fractionated stereotactic radiation therapy and intensity modulated radiosurgery. The Trilogy™ system delivers megavoltage x-ray treatments for therapeutic application in the treatment of cancer. The Trilogy™ system includes a dynamic multileaf collimator (Millennium™ MLC with Dynamic MLC software), electronic portal imaging device (AS1000™), asymmetric jaws, enhanced dynamic wedge, a stereotactic treatment delivery mode (6MV, 1000 MU/min, maximum field size of 15cm x 15cm) and remote couch motion. There will be a 0.75mm radius isocenter for all three rotational axes, which include the gantry, collimator and table axes. The Trilogy™ system will allow for stereotactic treatments that may be intracranial or extracranial and

consist of single-session or fractionated delivery. Stereotactic treatments are intended for therapy of lesions, *e.g.*, arteriovenous malformations, primary tumors and metastases.

5. Intended Use Statement: The Trilogy™ Radiotherapy Delivery System is a radiation therapy accelerator intended deliver megavoltage x-ray treatments for conventional radiotherapy (three dimensional conformal radiotherapy and intensity modulated radiotherapy) and stereotactic radiosurgery and radiotherapy. Stereotactic treatments are intended for therapy of lesions, *e.g.*, arteriovenous malformations, primary tumors and metastases. Stereotactic treatments may be intracranial or extracranial and consist of single-session or fractionated delivery.

6. Summary of the Technological Characteristics: The 2300 C/D, K913119 has been modified to modifications made to include radiotherapy stereotactic functionality and remote couch motions as new features. These modifications are substantially equivalent to the features of the Brainlab Novalis Shaped Beam Surgery System, K002509. The addition of these new features also result in a name change from the Varian Clinac to the Varian Trilogy™ Radiotherapy Delivery System. The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate devices. This chart is located in Tab 9 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

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

Re: K033343
Trade/Device Name: Trilogy Radiotherapy Delivery System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: October 16, 2003
Received: October 17, 2003

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 either class II (Special Controls) or class III (PMA), 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

510(k) Number (if known): K033343
Device Name: Trilogy Radiotherapy Delivery System

Indications For Use:

The Trilogy™ Radiotherapy Delivery System is a radiation therapy accelerator intended deliver megavoltage x-ray treatments for conventional radiotherapy (three dimensional conformal radiotherapy and intensity modulated radiotherapy) and stereotactic radiosurgery and radiotherapy. Stereotactic treatments are intended for therapy of lesions, *e.g.*, arteriovenous malformations, primary tumors and metastases. Stereotactic treatments may be intracranial or extracranial and consist of single-session or fractionated delivery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033343