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MAY 15 2006

VARIAN
medical systems

**Varian Medical Systems, Inc.**
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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
   Fax: (650) 842-5040
   Email: vy.tran@varian.com
   Date summary was prepared: April 21, 2006

2. Name of the Device: Trilogy Radiotherapy Delivery System and Trilogy Tx
   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'Trilogy Radiotherapy Delivery System –K033343
   b. Accuray's CyberKnife - K041315

4. Description of the Device: The Trilogy™ Radiotherapy Delivery System, K033343, is a dual-energy, high dose rate medical linear accelerator optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy and stereotactic applications. The Trilogy system allows for stereotactic treatments that may be intracranial or extracranial and consist of single-session or multi-session ("fractionated") treatment delivery.

5. Intended Use Statement: The Trilogy™ Radiotherapy Delivery and the Trilogy Tx is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

6. Substantial Equivalence – The Trilogy Radiotherapy Delivery is substantially equivalent to the predicate devices. The intended use, principles of operation, and technological characteristics are the same.

Substantial Equivalence Comparison Chart

The Trilogy™ Radiotherapy Delivery System and the Trilogy Tx Delivery System are substantially equivalent to the CyberKnife® System, K041315 for Intended Use and Indications for Use and are substantially equivalent to the Trilogy™ Radiotherapy Delivery System K033343 for features, design and operation.

The revised Intended Use and Indications for Use statements are equivalent to those used by CyberKnife.

| | CyberKnife® System for Stereotactic Radiosurgery/Radiotherapy, K041315 | Trilogy™ Radiotherapy Delivery System, K033343 | Trilogy™ Radiotherapy Delivery System | Trilogy Tx Delivery System |
|---|---|---|---|---|
| Intended Use | The CyberKnife System for Stereotactic Radiosurgery/Radiotherapy is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. | The Trilogy™ Radiotherapy Delivery System is a radiation therapy accelerator intended to 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 | The Trilogy™ Radiotherapy Delivery System is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. | The Trilogy Tx Delivery System is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. |

| | | | | |
|---|---|---|---|---|
| | | malformations, primary tumors and metastases. Stereotactic treatments may be intracranial or extracranial and consist of single-session or fractionated delivery. | | |
| Indications for Use | The CyberKnife System for Stereotactic Radiosurgery/Radiotherapy is indicated for treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. | The Trilogy™ Radiotherapy Delivery System is a radiation therapy accelerator intended to 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 | The Trilogy™ Radiotherapy Delivery System is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. | The Trilogy Tx Delivery System is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. |

| | | | | |
|---|---|---|---|---|
| | | of single-session or fractionated delivery. | | |
| Isocenter | Not Applicable | ≤1.5mm for all three rotational axes | ≤1.5mm for all three rotational axes | ≤1.5mm for all three rotational axes |
| Energy used | Not Applicable | 4-25MV | 4-25MV | 4-25MV |
| Dose rate | Not Applicable | 3DCRT and IMRT: Up to 600MU/min. SRS: Up to 1000MU/min | 3DCRT and IMRT: Up to 600MU/min. SRS: Up to 1000MU/min | 3DCRT and IMRT: Up to 600MU/min. SRS: Up to 1000MU/min |
| Maximum field size | Not Applicable | 3DCRT: 40cm x 40cm. IMRT: 34cm x 40cm. SRS: 15cm x 15cm | 3DCRT: 40cm x 40cm. IMRT: 34cm x 40cm. SRS: 15cm x 15cm | 3DCRT: 40cm x 40cm. IMRT: 34cm x 40cm. SRS: 15cm x 15cm |
| Remote couch motion | Not Applicable | Small, corrective motions (≤2cm and 2°) and large, planned rotations. Secondary position readout indicators perform secondary verification. | Small, corrective motions (≤2cm and 2°) and large, planned rotations. Secondary position readout indicators perform secondary verification. | Small, corrective motions (≤2cm and 2°) and large, planned rotations. Secondary position readout indicators perform secondary verification. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 15 2006

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

Re: K061140
Trade/Device Name: Trilogy Radiotherapy Delivery System and Trilogy Tx Delivery System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 20, 2006
Received: April 25, 2006

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 (Premarket Approval), 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 this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K061140
Device Name: Trilogy Radiotherapy Delivery System and Trilogy Tx Delivery System

Indications For Use:

The Trilogy™ Radiotherapy Delivery System and Trilogy Tx Delivery System are indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061140

Prescription Use ✓
(Per 21 CFR 801.109)