510(k) Summary

K062618

The information below is provided for the Trilogy Tx with 3rd Party Couch Top, following the format of 21 CFR 807.92.

SEP 22 2006

1. Submitter:

Varian Medical Systems
3100 Hansen Way, M/S e110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: 650/424.5731
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E-mail: vy.tran@varian.com

2. Name of the Device:

Trade / Proprietary Name:	Trilogy Tx with 3rd Party Couch Top Support Trilogy Tx Delivery System
Common or Usual Name:	Trilogy Tx
Classification Name:	Medical Charged Particle Radiation Therapy System 21 CFR §892.5050 Class II
Product Code:	90 IYE

3. Predicate Device to claim substantial equivalence:
   Varian Medical Systems' Trilogy Tx Radiotherapy Delivery System – K061140

4. Description of the Device:

   The Trilogy Tx Delivery System is being modified to include 3rd Party Couch Top Support.

   The Exact couch patient positioning and support within the Trilogy Tx cleared device is partially accomplished by the motorized control of longitudinal, lateral, vertical and angular positions. The Exact couch top, also known as the couch stretcher top or the treatment table top is fastened to the Exact couch and is the primary portion of the couch for positioning and support. An Exact couch interface specification is available to non-Varian aftermarket couch top manufacturers for use in designing couch tops that are used on the Exact couch instead of the Varian Exact couch top.

   3rd Party Couch Top Support (also known as Aftermarket "non-Varian" Couch Top Attachment) enables third party couch tops to be installed upon the Exact Couch base, replacing the original Varian Exact Couch Top. The replacement is implemented following a published Interface Specification. Physical installation is completed and qualified by Varian representatives at customer locations, following proprietary internal procedures to ensure safety and effectiveness equivalent to that of the original Exact Couch Top.

5. Intended Use Statement

   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.

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6. Indications for Use Statement

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.

The 3rd Party Couch Top Support is designed to position and support patients for radiotherapy. The Varian Exact ® Couch is designed for use with non-Varian aftermarket table tops.

7. Substantial Equivalence

The 3rd Party Couch Top submission illustrates substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 2 2 2006

Mr. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems
3100 Hansen Way, M/S/ E-110
PALO ALTO CA 94304

Re: K062618
Trade/Device Name: Trilogy Tx with 3rd Party Couch Top Support
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 31, 2006
Received: September 5, 2006

Dear Mr. 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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

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Indications for Use Statement

510(k) Number (if known): K062618

Device Name: TRilogy Tx w 3rd Party Couch Top Support

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.

The 3rd Party Couch Top Support is designed to position and support patients for radiotherapy. The Varian Exact ® Couch is designed for use with non-Varian aftermarket table tops.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter _____
(Per 21 CFR § 801.109)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062618