K071992

510(k) Summary

AUG 15 2007

The information below is provided for the High-Definition 120 Multileaf Collimator (HD120 MLC), following the format of 21 CFR 807.92.

1. Submitter: Varian Medical Systems
   3100 Hansen Way, M/S e110
   Palo Alto, CA 94304
   Contact Name: Vy Tran
   Phone: 650/424.5731
   Fax: 650/842.5040
   E-mail: vy.tran@varian.com

2. Name of the Device: High-Definition 120 Multileaf Collimator (HD120 MLC)
   Trade / Proprietary Name: High-Definition 120 Multileaf Collimator (HD120 MLC)
   Common or Usual Name: Accessory to Medical Linear Accelerator
   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:
   Varian Medical Systems Millennium Multileaf Collimator – K050442

4. Description of the Device:

   The High-Definition 120 Multileaf Collimator (HD120 MLC) provides higher resolution via finer width leaves in the center section of the treatment field. The total number of leaves remains the same at 120. As a result of the finer leaves, the treatment field has been modified from 40 cm to 22 cm in width. The length of the treatment field remains unchanged.

   The objective of the area occupied by the finer leaves is to provide for higher definition shaping of treatment fields. These fields are primarily directed at small targets during single fraction Stereotactic Radiosurgery (SRS) and multi-fraction Stereotactic Radiotherapy (SRT).

5. Intended Use Statement

   The Varian High-Definition 120 Multileaf Collimator (HD120 MLC) is an accessory X-ray collimator designed to be mounted on Varian Trilogy Tx and Trilogy linear accelerators and is intended to shape the X-ray field perimeter. Field shape can be either static (fixed) or dynamic. Dynamic field shapes are controlled as a function of the accelerator dose fraction or gantry angle. The intended use is to assist the clinician in the delivery of radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

6. Indications for Use Statement

The Varian High-Definition120 Multileaf Collimator (HD120 MLC) is provided to assist the clinician in the delivery of external beam radiation to defined target volumes during radiosurgery and radiotherapy while sparing surrounding normal tissue and critical organs from excess radiation.

7. Substantial Equivalence

The High-Definition 120 Multileaf Collimator (HD120 MLC) submission illustrates substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 15 2007

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

Re: K071992
Trade/Device Name: High-Definition 120 Multileaf Collimator (HD120 MLC)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 19, 2007
Received: July 20, 2007

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.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

VARIAN medical systems

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Indications for Use Statement

510(k) Number (if known): K071992

Device Name: High-Definition 120 Multileaf Collimator (HD120 MLC)

Indications for Use:

The Varian High-Definition 120 Multileaf Collimator (HD120 MLC) is provided to assist the clinician in the delivery of external beam radiation to defined target volumes during radiosurgery and radiotherapy while sparing surrounding normal tissue and critical organs from excess radiation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071992