K133240

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VARIAN medical systems
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January 7, 2014

**510(k) Summary**

The information below is provided for the Varian Multileaf Collimator, following the format of 21 CFR 807.92.

1. 510(k) Owner: Varian Medical Systems
   3100 Hansen Way, M/S C 260
   Palo Alto, CA 94304
   Contact Name: Peter J. Coronado - Director, Regulatory Affairs
   Phone: 650/424.6320
   Fax: 650/842.5040
   E-mail: submissions.support@varian.com

2. Name of the Device: Varian Multileaf Collimator (MLC)
   Trade/Proprietary Names: Millennium 52-leaf Multileaf Collimator
   Millennium 80-leaf Multileaf Collimator
   Millennium 120-leaf Multileaf Collimator
   High-Definition 120 Multileaf Collimator (HD120 MLC)

   Common 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 Device: High-Definition 120 Multileaf Collimator K071992

4. Description of the Device:

   The Varian Multileaf Collimator (MLC) is an accessory X-ray collimator designed to be mounted on a Varian radiotherapy linear accelerator.

   The Multileaf Collimator (MLC) head is mounted on a Varian Linear Accelerator, where it shapes the radiation beam before it is delivered to the patient. The MLC head is permanently bolted onto the casting that holds the X-Jaws and Y-Jaws of the Varian Linear Accelerator gantry.

The MLC head assembly contains two leaf banks, plus associated electromechanical components. The MLC head is located behind covers during operation, which prevent unintended contact with any person.

The MLC leaves reside in two carriages. Each leaf is driven by an independent motor. When shaping the radiation field perimeter to conform to the tumor outline, adjacent MLC leaves from opposing banks can move past one another. This feature, known as leaf inter-digitation, allows for the creation of complex shapes.

The two carriage drives are independently controlled. Smooth motion of the leaves and carriages is achieved using a trapezoidal velocity profile that ramps up speed of the leaves or carriages to a fixed speed, and then ramps speed down until the leaf (or carriage) stops precisely at the final position.

The various MLC models provide varying numbers and widths of leaves. The leaf banks extend over different widths within the Multileaf Collimator, for the 52-leaf, 80-leaf, and the 120-leaf Millennium MLC, and the HD120 MLC models. The Varian Multileaf Collimator (MLC) head contains many computer-controlled mechanical "leaves" or "slats" that continually shape the treatment beam as the radiation is delivered from different angles around the patient.

The changes to the Varian Multileaf Collimator provide updates for electronics and information technology hardware, improvements in usability and serviceability, and additional discrepancy fixes. The operation and intended use of the device remain unchanged. Overall safety of the device is unchanged.

All other features and technological characteristics of the Varian Multileaf Collimator are unchanged compared to the Varian predicate device cleared in K071992.

5. Intended Use Statement

The Varian Multileaf Collimator is intended 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.

6. Indications for Use Statement

The Varian Multileaf Collimator is intended 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 modified device, the Varian Multileaf Collimator (MLC), is substantially equivalent to the predicate device of K071992.

Compared with the predicate device, the basic operation and technological characteristics are the same. Operational differences are described in the Instructions for Use and accompanying user documentation. The indications for use and the intended use of the device are changed.

A comparison table illustrating the substantial equivalence of the modified device to the predicate device appears below.

Changes in Technological characteristics:

| DESCRIPTION | MULTILEAF COLLIMATOR K071992 | VARIAN MULTILEAF COLLIMATOR |
|---|---|---|
| Release version of control software | MLC 7.0 | MLC 8.0 |
| Support for Millennium 52-leaf, 80-leaf ,120-leaf, and HD120 MLC models | yes | yes |
| Support for Saturne MLC, Mark Series controllers and BrainLab m3 MLC | yes | no |
| Support for digitizer panel hardware | yes | no |
| Support for 3rd party interface (3PI) | yes | no |
| Screen color scheme is that of 4DITC as default | no | yes |
| System offset diagnostics facilitate the transfer of patients between 6.x and 7.x machines | no | yes |
| Supports local languages (non-English) on screen display, including Unicode compliance for display of extended language character sets | no | yes |
| Zoom capability for MLC leaf position display | no | yes |
| Improved ZIP file creation for system information capture | no | yes |
| Updated electronics: Low Profile Controller Unit | no | yes |
| Instructions for Use document adds recommendations on jaw positions to minimize out-of-field dose from scattered radiation | no | yes |
| Visual display of Complete Irradiated Area Outline is calculated using a common system-wide component | no | yes |
| Capability to use either 4:3 or 16:9 display ratio monitor | no (4:3 ratio only) | yes |

| DESCRIPTION | MULTILEAF COLLIMATOR K071992 | VARIAN MULTILEAF COLLIMATOR |
|---|---|---|
| Shaper software application is used for manual creation of treatment plans | yes | No (used for Physics and Service analysis only) |
| Warning message when the MLC is in use but the Varian 4D Integrated Treatment Console (4DITC) software (K091132) is not also in use: "This mode is not to be used for clinical treatments." | no | yes |

8. Summary of Non-Clinical Testing

Verification testing was performed to demonstrate that the performance and functionality of the new and existing features met the design input requirements.

Regression testing was performed to verify the integrity of any changes. Validation testing was performed on a production equivalent device, under clinically representative conditions by qualified personnel.

9. Conclusions from Non-Clinical testing

Results from Verification and Validation testing demonstrate that the product met defined user needs and defined design input requirements. Varian therefore considers the Multileaf Collimator to be safe and effective, and to perform at least as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Varian Medical Systems, Inc.
% Mr. Peter Coronado
Director, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

January 31, 2014

Re: K133240
Trade/Device Name: Varian Multileaf Collimator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: Oct. 17, 2013
Received: Oct. 21, 2013

Dear Mr. Coronado:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K133240

Device Name: Varian Multileaf Collimator

Indications For Use:

The Varian Multileaf Collimator 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.

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)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K133240_____