



Premarket Notification [510K] Summary  
as required by 21 CFR 807.92

Date Summary was prepared:  
January 8, 1999

Submitter's Name:  
Varian Oncology Systems  
3045 Hanover Street  
Palo Alto, CA 94304

Contact Person:  
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Regulatory Compliance & Radiation  
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Device Name:  
Millennium MLC - 120

Classification Name:  
Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Predicate Device:  
Varian Multileaf Collimator with Dynamic Arc Therapy, K973889

Product Description:  
The Varian Millennium Multileaf Collimator (MLC) is an x-ray collimator designed to be mounted on a C or EX Series Varian Clinac® radiation therapy linear accelerator beneath the standard field defining the collimator jaw.



**Intended Use:**

The Varian Millennium Multileaf 120 Collimator (MLC) is an x-ray collimator designed to be mounted on a C or EX Series Varian Clinac® radiation therapy linear accelerator and is intended to shape the x-ray field perimeter. Field shape can either be static (fixed) or dynamic. Dynamic field shapes are controlled as a function of either Clinac® dose fraction or gantry angle. The intended use is to assist the radiation oncologist in the delivery of radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

**Technological Characteristics:**

See the attached "Specification Comparison Chart" (Tab F).



FEB 8 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Linda Nash  
Regulatory Compliance  
And Radiation Safety Manager  
Varian Associates, Inc.  
3045 Hanover Street  
Palo Alto, CA 94304-1129

Re: K990085  
Millenium MLC-120 (Multileaf Collimator)  
Dated: January 8, 1999  
Received: January 11, 1999  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Nash:

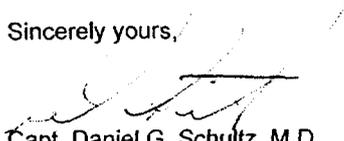
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

  
Capt. Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications For Use**

510(k) Number (if known): K990085

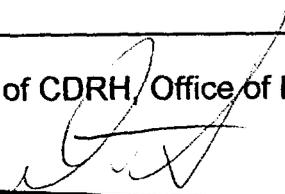
Device Name: Millennium MLC - 120

**Indications for Use:** The Varian Millennium 120 Multileaf Collimator (MLC) is provided to assist the radiation oncologist in the delivery of radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. In a static mode, the MLC performs the same function as the customized shadow blocks. In a dynamic mode, a series of MLC leaf positions can be indexed to either Clinac® dose fraction or gantry angle to create a changing beam shape while the radiation beam is on to create a three dimensional dose distribution.

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

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Concurrence of CDRH/Office of Device Evaluation (ODE)

  
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(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K990085

Prescription Use    
(per 21 CFR 801.109)

OR

Over-The-Counter Use