

K973889



**Summary of Safety and Effectiveness  
Information**

NOV 21 1997

1. **Submitter:** Varian Oncology Systems  
3045 Hanover Street  
Palo Alto, CA 94304
- Contact:** Charles H. Will, Manager  
Regulatory Compliance & Safety  
Phone (650) 424-5036  
FAX (650) 424-4830  
cwill@os.varian.com
- Prepared:** October 13, 1997
2. **Device Name:** Varian MultiLeaf Collimator with dynamic arc therapy feature
3. **Predicate Devices:** Varian MultiLeaf Collimator (K926449, K943224)  
BrainLAB micro-MultiLeaf Collimator (K970586)
4. **Description:** The Varian MultiLeaf Collimator (MLC) is an x-ray collimator designed to be mounted on a Varian Clinac® radiation therapy linear accelerator beneath the standard field defining collimator jaws to provide complex beam shaping supplementary to the Clinac's rectangular fields. It contains either 52 or 80 collimator leaves (26 or 40 opposed pairs of leaves), each of which can be positioned individually in order to provide an irregularly shaped treatment field that corresponds closely with the volume intended to be irradiated. With the dynamic arc therapy feature, the leaves may be continuously repositioned as a function of the Clinac gantry position during rotational irradiation (arc therapy) in order to provide dynamic conformal therapy.
5. **Intended Use:** The Varian 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 this the MLC performs the same

function as customized shadow blocks. Employing the MLC Arc Therapy feature enables movement of individual leaves of the MLC according to a pre-existing schedule while the host Clinac linear accelerator is performing arc therapy. In this modality the beam shape created by the MLC can correspond to a beam's eye view of the treatment volume at all times while the gantry is rotating in arc therapy.

**6. Technological  
Considerations:**

The MLC version being reported in this 510(k) Notification is, from a hardware standpoint, identical to the MLC reported in prior 510(k)'s (K926449 and K943224). The software to be provided with the MLC version notified herein contains the capability to provide dynamic arc therapy as described above.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 21 1997

Charles Will  
Manager Regulatory Compliance & Safety  
Varian Associates, Inc.  
3045 Hanover Street  
Palo Alto, California 94304

Re: K973889  
Varian Multileaf Collimator with Dynamic arc Therapy  
Dated: October 13, 1997  
Received: October 14, 1997  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Will:

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 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 requirement, 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



Statement of Indications for Use\*

I state in my capacity as Manager, Regulatory Compliance and Safety, of Varian Oncology Systems that the Product which is the subject of this premarket notification is intended to be used for the following:

The Varian 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 this the MLC performs the same function as customized shadow blocks. Employing the MLC Arc Therapy feature enables movement of individual leaves of the MLC according to a pre-existing schedule while the host Clinac® linear accelerator is performing arc therapy. In this modality the beam shape created by the MLC can correspond to a beam's eye view of the treatment volume at all times while the gantry is rotating in arc therapy.

Charles H. Will
Charles H. Will, Manager
Regulatory Compliance & Safety

October 13, 1997
Date

\*Suggested language and format to meet the requirements of section 513(l) of the Federal Food, Drug, and Cosmetic Act, as amended, and 21 CFR sections 801.4 and 809.92(a)(5).

K9 73889
510(k) Number

Division Sign-off
Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109) Over-the-Counter Use