

DEC 15 1999

Section 5: 510(k) Summary

K993594

MMLC 510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

Submitter of Premarket Notification:

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Establishment Registration Number:

1222895

Performance Standards:

No applicable performance standards have been issued under section 514 of the Food, Drug & Cosmetic Act.

Device Name:

Mini Multi-Leaf Collimator (MMLC VR1)

Common Name:

Radiotherapy beam shaping block

Safety Summary:

Radionics Software Applications' MMLC VR1 system testing verifies that the software is ready for clinical use. A rigorous test of the functionality of the MMLC-Siemens interface was conducted using a Siemens LINAC, equipped with PrimeView and Lantis. The LINAC was equipped with the Radionics MMLC interface hardware (BCI box).

Predicate Device:

Radionics MMLC: 510(k) # K982549, dated December 30, 1998.

Intended Use:

The intended use for the MMLC VR1 is:

The MMLC is intended to assist the radiation oncologist team in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. This is accomplished through 31 pairs of opposing tungsten leaves, which allow the MMLC to shape the x-ray beam according to a treatment plan generated by a planning system such as the RSA XPlan software.

Device Description:

The Mini Multi-Leaf Collimator (MMLC) is a complete system consisting of an independent device that attaches to a Siemens linear accelerator (LINAC) for small field conformal radiosurgery or radiotherapy. Along with XPlan Conformal Treatment Planning Software, the MMLC enables static conformal treatments to be performed with finely shaped field patterns created by independently actuated leaves.

The subject of this submission, the software modifications for the MMLC VR1, is for use in an installation of a Siemens LINAC with the Lantis Verify and Record system and the PrimeView front end. This program coordinates MMLC settings with the Siemens software and hardware and assures that the MMLC is set correctly to the same field as the LINAC setting, and can abort treatment if the MMLC cannot be set correctly.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nancy MacDonald
Senior Regulatory Affairs Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K993594
Radionics ConforMAX MMLC VR1
Dated: November 23, 1999
Received: November 24, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. MacDonald:

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

ODE Indications for Use Statement

510(k) Number (if known): K993594

Device Name: MMLC VR1

Indications for Use:

The MMLC is intended to assist the radiation oncologist team in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. With Radionics' XPlan Conformal Treatment Planning Software or any treatment planning system, the MMLC enables static conformal treatments to be performed with finely shaped field patterns. In this application, the MMLC performs the same function as customized beam shaping blocks, and circular or cut block collimators, which have been used for many years.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR § 801.109)

OR

Over-the-Counter Use

David A. Nyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993594