DEC 30 1998

Model MMLC
Radionics Mini Multi-Leaf Collimator
510 (k)

Section I: General Device Summary

K982549

Proprietary Name: Model MMLC Radionics Mini Multi-Leaf Collimator

Common Name: Radiotherapy beam shaping block

Product Code/Classification Panel: IYE / Radiology

Classification: Class II
§892.5710

Summary of Safety and Effectiveness

The 510(k) Summary of Safety and Effectiveness is provided in **Appendix A.**

Performance Standards

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

Voluntary Standards

- EN55011: Electromagnetic Disturbances
  Class A, Group 1, ISM
- EN 60601-1-2: Collateral Standard
  Electromagnetic Compatibility
  Medical Electrical Equipment
- EN 60601-1: Medical Electrical Equipment
- UL 2601: Medical Electrical Equipment
  Part 1: Requirements for Safety

Section I: General Device Summary *(Continued)*

Establishment Registration

Manufacturing Facility Address:

Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803

FDA Establishment Registration No.: 1219140

Sterilization Site:

No part of this device is supplied sterile.

Predicate Devices

Brainlab Micro Multi-Leaf Collimator (K970586) manufactured by Brainlab Medical Computersysteme GmbH (hereafter referred to as "Brainlab MLC")

Section I: General Device Summary *(Continued)*

1.0 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. 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. XPlan is a stereotactic LINAC-based radiation treatment planning software and was previously cleared under 510(k) K972905. In this application, the MMLC performs the same function as customized beam shaping blocks or stereotactic collimators, which have been used for many years.

1.1 Device Characteristics

The MMLC is a conformal radiation therapy and radiosurgery device. The MMLC is mounted to a standard radiation therapy LINAC and is capable of shaping the x-ray field (maximum field treatment of 10 cm x 12 cm). A stand-alone computer controls the MMLC unit. The computer communicates with the MMLC to position the leaves according to the treatment plan. An individual motor controls each leaf. Power to the motors and electronics is provided by a switching power supply.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1998

David Cromwick
Director of Regulatory Affairs and Quality Assurance
Radionics® Inc.
22 Terry Avenue
Burlington, MA 01803-2516

Re: K982549
Mini Multileaf Collimator
Dated: October 23, 1998
Received: October 26, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Cromwick:

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

Section II: Indications for Use

2.0 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.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982549

Prescription Use ✓
(Per 21 CFR 801.109)