7.0 510(k) Summary: SEP 2 1 1999 K991399

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 C.F.R. 807.92.

1.0 The submitter of this premarket notification is:

Kevin J. O'Connell
Regulatory Engineer
Radionics Software Applications, Inc,
22 Terry Avenue
Burlington, MA 01803
Tel.: (781) 272-1233
Fax: (781) 272-2428

This summary was prepared on April 19, 1999.

2.0 The name of the device is the Radionics Microelectrode Kit (MEK). The common name is recording and lesioning electrode kit, and its classification names are Depth electrode and Radiofrequency lesion probe

3.0 The above device is substantial equivalent to the TM and TCM electrodes which where commercially available prior to May 28, 1976.

4.0 The above device consists of a recording electrode, lesion electrode, sheath, adaptor bushing, spacer and passing cannula. It is used with the Nueromap System, CRW Stereotaxtic frame and lesion generator to record signals in determining the placement of lesions.

5.0 The device like its predicates is intended for recording, stimulating and lesioning nervous tissue for functional neurosurgical procedures such as but not limited to: cordotomies, tractotomies, myelotomies, thalamotomies and pallidotomies.

6.0 The technological characteristics are the same or similar to those found with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 1999

Mr. Kevin J. O'Connell
Regulatory Engineer
Radionics, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K991399
Trade Name: Radionics Microelectrode Kit
Regulatory Class: II
Product Code: GXI
Dated: July 20, 1999
Received: July 22, 1999

Dear Mr. O'Connell:

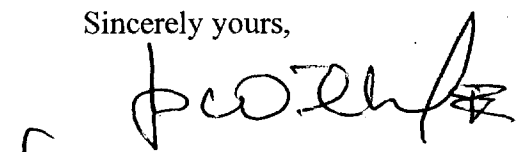
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991399

Device Name: Radionics Microelectrode Kit

Indications for use: For recording, stimulating and lesioning nervous tissue for functional neurosurgical procedures such as but not limited to: cordotomies, tractotomies, myelotomies, thalamotomies and pallidotomies.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991399

PRESCRIPTION USE X OR Over-The-Counter Use ___

(Per 21 CFR 801.109

(Optional Format 1-2-96)