K961942

Appendix A:

AUG 1 8 1997

Summary of Safety and Effectiveness

I. General Information

Common Name:	Cortical Surface and Depth Electrodes
Device Trade Name:	Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring
Classification:	Class II 882.1310 Cortical Electrode 882.1330 Depth Electrode
Intended Use:	Radionics Epidural Peg, Sphenoidal and Foramen Ovale Depth Electrodes are intended for intraoperative recording of electrical signals for epilepsy monitoring at the surface and subsurface levels of the brain.
Predicate Device:	Radionics Cortical Surface & Depth Electrodes (K926424).
Manufacturing Facility Address:	Radionics, Inc. 76 Cambridge St. Burlington, MA 01803
Performance Standard:	No applicable performance standards have been issued under section 514 of the Food, Drug, and Cosmetic Act.
Establishment Registration Number:	1219140
Product Code/Classification Panel:	84GYC & 84GZL/Neurology
Contact Name and Address:	Amy J. LaForte, Ph.D., (617) 272-1233 Radionics, Inc. 22 Terry Ave. Burlington, MA 01803

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

A summary of the information contined in this PMN that addresses safety and effectivness follows.

General Safety and Effectiveness Concerns

Radionics Epidural Peg, Sphenoidal, and Foarmen Ovale Depth Electrodes labeling contains instructions for the proper use of this product. It includes a description of the product, directions for use, and applicable safety information. These instructions ensure

safe and effective use of the device when followed by the physician.

Description of the Device and Basis for Substantial Equivalence

The Epidural Peg, Sphenoidal, and Foramen Ovale Depth Electrodes addressed in this PMN have similar intended uses, materials, technological characteristics, sterilization procedures, and packaging as the commercially available Radionics Cortical Surface and Depth Electrodes (K926424). These electrodes are used for intraoperative recording of electrical signals for epilepsy monitoring at the surface and subsurface levels of the brain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1997

Amy J. LaForte, Ph.D.
Manager Regulatory Submissions
Radionics, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K961942
Trade Name: Radionics Epidural Peg, Sphenoidal, and Foramen Ovale Electrodes
Regulatory Class: II
Product Code: 84GYC and 84GZL
Dated: June 30, 1997
Received: July 2, 1997

Dear Dr. LaForte:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

electrode

Indications for Use

Radionics Epidural Peg, Sphenoidal and Foramen Ovale Depth Electrodes are indicated for intraoperative recording of electrical signals for epilepsy monitoring at the surface and subsurface levels of the brain.

Prescription Use ✓
(Per 21 CFR 801.109)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K961942