AUG 4 2000

K992226

Attachment V: Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER:	Radionics Inc, 76 Cambridge Street Burlington, MA 01803 Tel.: (781) 272-1233 Fax: (781) 272-2428 Contact: Kevin J. O'Connell Regulatory Engineer
PROPRIETARY NAME:	Radionics External CSF Drainage and Monitoring System (XDS)
COMMON OR USUAL NAME:	External Drainage System
CLASSIFICATION CODE:	Shunt, Central Nervous System and Components 21 CFR, Section: 882.5550
PREDICATE DEVICE:	Medtronic Becker External Drainage and Monitoring System, K984053
DESCRIPTION:	The XDS provides a simple to use, closed loop system for the drainage of cerebrospinal fluid (CSF) and allows for pressure monitoring. XDS consists of a disposable drainage bag attached to a drainage tubing set that incorporates a calibrated scale and a graduated drip chamber used for estimation of drainage fluids. The systems will be provided sterile and will be labeled for single use only.
INTENDED USE:	The XDS allows for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and the monitoring of ICP.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Mr. Kevin J. O'Connell
Senior Regulatory Associate
Radionics, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K992226
Trade Name: External CSF Drainage and Monitoring System
Regulatory Class: II
Product Code: JXG
Dated: May 9, 2000
Received: May 10, 2000

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,

Donna R. Bochner

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

Enclosure

2.0 ODE Indications Statement

510(k) Number (if known): K992226

Device Name: Radionics External CSF Drainage and Monitoring System

Indications for use: Allows for drainage and monitoring of cerebrospinal fluid (CSF) from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and the monitoring of ICP.

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

Donna R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992226

PRESCRIPTION USE ✓ OR Over-The-Counter Use ___

(Per 21 CFR 801.109

(Optional Format 1-2-96)