

SEP 8 1999

K992379

Attachment VI: 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 XDC Ventricular Catheter

COMMON OR USUAL NAME: External Drainage Ventricular Catheter

CLASSIFICATION CODE: Shunt, Central Nervous System and Components
21 CFR, Section: 882.5550

PREDICATE DEVICE: Clinical Neuro System's MoniTorr ICP™ Ventricular Catheter, K922941
Medtronic Becker EDM Ventricular Catheters, 510(k) unk

DESCRIPTION: The External Drainage Ventricular Catheter consists of a barium impregnated silicone tubing with flow holes at the distal end and a luer lock connector for attachment to an external drainage system. It is provided sterile for single use only.

INTENDED USE: As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1999

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

Re: K992379
Trade Name: Radionics XDC Ventricular Catheter
Regulatory Class: II
Product Code: JXG
Dated: July 15, 1999
Received: July 16, 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.

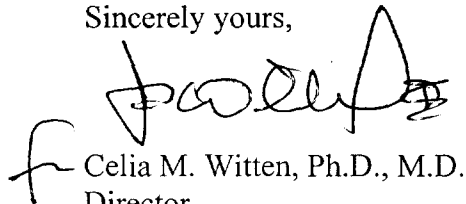
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Kevin J. O’Connell

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized initial 'C' and a horizontal line extending to the right.

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

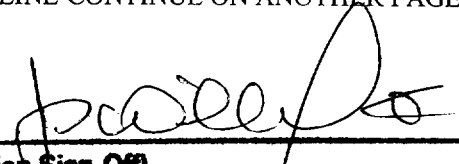
2.0 ODE Indications Statement:

510(k) Number (if known): K992379

Device Name: Radionics XDC Ventricular Catheter

Indications for use: As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.

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



(Division Sign-Off)
Division of General Restorative Devices K992379
510(k) Number _____

PRESCRIPTION USE X

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)