

APPENDIX A: Summary of Safety and Effectiveness

K980430

MAR 16 1998

K 980430

I. General Information

Proprietary Trade Name: Radionics Disposable RF cannulae

Model Numbers: SC-C, RK-DS, RFK-DB

Common Name: Disposable cannula for radiofrequency electrode

Manufacturing Facility Address: Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803

Establishment Registration Number: 1219140

Contact Person: William Rittman
(781) 272-1233

Classification / Panel: Class II / Neurology

Predicate Devices: RSM-C Cannula (K963577);
SMK-C Cannula (K870028).

Intended Use: The SC-C, RFK-DS and RFK-DB are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain. This is the same intended use as the RSM-C Cannula and SMK-C Cannula.

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

Sterilization Site: STS
7500 W. Henrietta Road
PO. Box 349
Rush, NY 14543
(716) 533-1672

General Information (Continued from page A-1)

The SC-C, RFK-DS and RFK-DB Radionics disposable RF Cannulae are insulated disposable cannulae designed for use with a Radionics Radiofrequency Lesion Generator to create heat lesions for relief of pain.

The SC-C cannulae are compatible with the commercially available Radionics SMK-TC thermocouple electrodes. They are used in the same way as the commercially available Radionics RSM-C and SMK-C cannulae. The RFK-DS and RFK-DB are compatible with the commercially available RFK-TC thermocouple electrode. They are used in the same way as the commercially available Radionics RSM-C and SMK-C cannulae.

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

General Safety and Effectiveness Concerns

Radionics Disposable RF Cannula (SC-C, RFK-DS and RFK-DB) labeling contains instructions for the proper use of this device. 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

Radionics Disposable RF Cannula (SC-C, RFK-DS and RFK-DB) addressed in this premarket notification has similar intended use and technological characteristics as the commercially available Radionics RSM-C cannulae (K963577) and SMK-C cannulae (K870028). The insulating material is widely used as a medical grade heat shrinkable tubing and biocompatibility has been performed on Radionics SC-C10 Cannula.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1998

Mr. William J. Rittman III
Vice President
Radionics, Incorporated
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K980430
Trade Name: Radionics Disposable RF Cannulae
(SC-C, RFK-DB, RFK-DS)
Regulatory Class: II
Product Code: GXI and GXD
Dated: January 30, 1998
Received: February 4, 1998

Dear Mr. Rittman:

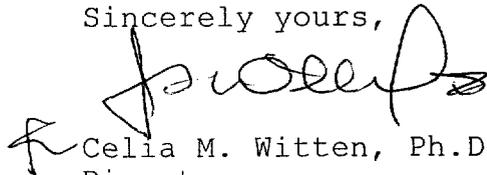
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 pre-market 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): K980430

DEVICE NAME: Radionics Disposable RF Cannulae (SC-C, RFK-DB, RFK-DS)

INDICATIONS FOR USE:

The SC-C, RFK-DS, and RFK-DB cannulae are indicated for use in RF heat lesion procedures for the relief of pain.

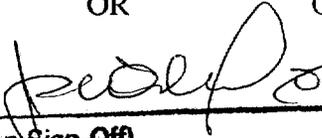
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use (Optional Format 1-2-96)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K980430