APR 0 4 2003

Section 6: 510(k) Summary

Radionics Single Use Grounding Pad (DGP-HP) 510(k) Summary

K030697

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
Senior Regulatory Associate
Radionics, a division of Tyco Healthcare Group LP
22 Terry Avenue
Burlington, MA 01803
Tel.: (781) 272-1233
Fax: (781) 272-2428

This summary was prepared on March 4, 2003.

2.0 The name of the device is the Radionics Single Use Grounding Pad. The common name is Electrosurgical Grounding Pad, and its classification name is Electrosurgical Coagulation Device Accessory.

3.0 The above device is substantial equivalent to the Radionics RFG-DGP Disposable Grounding Pad that was cleared via 510(k), K923647, on November 9, and the Nikopad Electrosurgical Grounding Pad Model 4777M that was cleared via 510(k), K000079, on February 4, 2000.

4.0 The Radionics Disposable Grounding Pad, DGP-HP, is a dispersive electrode that self adheres to the patients skin. The pad consists of an electrode element made up of a rubberized foam backing, a conducting plate, and a conductive gel. The electrode element is joined to a cable and standard connector that interfaces with an RF generator.

5.0 The device like its predicates is intended for use as the dispersive electrode during radiofrequency lesioning procedures. The DGP-HP is specifically indicated for use with the Radionics Cool-tip™ RF System.

6.0 The grounding pad is designed to conform to the applicable sections of ANSI/AAMI HF18-1993, IEC 60601-2-2, 1998, and ISO 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 4 2003

Mr. Kevin J. O'Connell
Senior Regulatory Associate
Radionics, A Division of Tyco Healthcare Group LP
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K030697
Trade/Device Name: Radionics Single Use Ground Pad (DGP-HP)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 4, 2003
Received: March 6, 2003

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

ODE Indications for Use Statement

510(k) Number (if known): K030697

Device Name: Radionics Single Use Ground Pad (DGP-HP)

Indications for Use:

The Radionics DGP-HP Single Use Ground Pad is to be used with the Radionics Cool-tip™ RF System.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use

(Per 21 CFR § 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030697