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General Device Summary

Device :	Cosman RF Lesion Generator, Model RFG-1A, and associated Radiofrequency Lesion Probes
Proprietary Trade Name:	Cosman RF Lesion Generator, Model RFG-1A Cosman Radiofrequency Lesion Probes
Manufacturer:	Cosman Medical, Inc. 76 Cambridge St., Burlington MA 01803. USA Tel. 781-272-6561. Fax 781-272-6563
Contact Name:	Michael Arnold, Director of RA/QA email: marnold@cosmancompany.com
Establishment Registration No.:	Number not assigned
Sterilization Site Address:	No part of this device is supplied sterile.
Classification:	882.4400, Radiofrequency Lesion Generator, Class II Neurology Devices, Product Code: GXD 882.4725, Radiofrequency Lesion Probe, Class II Neurology Devices, Product Code: GXI
Performance Standard:	No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug, and Cosmetic Act.
Predicate Devices:	Radionics RFG-3C Plus Lesion Generator (K982489) Radionics SMK Sluijter-Mehta Kit (K870028, K963577,K980430 and Preamendment Devices) Radionics Microelectrode Kit (K991399) Diros Technology URF-2AP Lesion Generator (K021869) Diros Technology URP-2A and Associated Radiofrequency Probes (K010202)

Intended Use: The Cosman RF Lesion Generator, Model RFG-1A, and associated Radiofrequency Lesion Probes, is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures.

Device Equivalence: The Cosman RF Lesion Generator, Model RFG-1A, and associated Radiofrequency Lesion Probes have been compared to previously 510(k) cleared devices with respect to intended use and technological characteristics. Performance testing was done to

results in this 510(k) notification show that the Cosman RF Lesion Generator, Model RFG-1A, and associated Radiofrequency Lesion Probes are substantially equivalent to predicate devices and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Mr. Michael Arnold
Director of RA/QA
Cosman Medical, Inc.
76 Cambridge Street
Burlington, Massachusetts 01803

Re: K050084
Trade/Device Name: Cosman RF Lesion Generator, Model RFG-1A
Cosman Radiofrequency Lesion Probes
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI, GXD
Dated: January 11, 2005
Received: January 13, 2005

Dear Mr. Arnold:

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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050084

Device Name: Cosman RF Lesion Generator, Model RFG-1A and associated Radiofrequency Lesion Probes

Indications For Use:

"The Cosman Radiofrequency Lesion Generator, Model RFG-1A, and associated Radiofrequency Lesion Probes, is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. "

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050084