

OCT 16 2008

K082051

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510(k) Summary

Device Name: Cosman G4 Radiofrequency Generator

Common Name: G4

Manufacturer: Cosman Medical, Inc.
76 Cambridge St., Burlington MA 01803. USA
Tel. 781-272-6561. Fax 781-272-6563

Contact Name: Louis Falcone, Director of RA/QA
email: lfalcone@cosmanmedical.com

Establishment Registration No.: 3004867882

Classification: 882.4400, Radiofrequency Lesion Generator, Class II
Neurology Devices, Product Code: GXD

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: Cosman RF Lesion Generator, model RFG-1A
(FDA Substantial Equivalence, K050084)

NeuroTherm RF Pain Management Generator NT1000
(FDA Substantial Equivalence, K052878)

Statement of Intended Use: The Cosman G4 Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. The Cosman G4 Radiofrequency Generator is used with separately approved Cosman Radiofrequency Probes.

Device Substantial Equivalence: The Cosman G4 Radiofrequency Generator has been compared to previously 510(k) cleared devices with respect to intended use and technological characteristics. Performance testing was done to validate the intended use of the Cosman device. The comparison and performance test results in this 510(k) notification show that the Cosman G4 Radiofrequency Generator is substantially equivalent to the predicate devices and is safe and effective for the intended use.



OCT 16 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cosman Medical, Inc.
% Mr. Louis Falcone
Director, RA/QA
76 Cambridge Street
Burlington, Massachusetts 01803

Re: K082051

Trade/Device Name: Cosman G4 Radiofrequency Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator.
Regulatory Class: II
Product Code: GXD
Dated: September 08, 2008
Received: September 26, 2008

Dear Mr. Falcone:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: (if Known)

K082051

Device Name: Cosman G4 Radiofrequency Generator

Indications for Use Statement: The Cosman G4 Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. The Cosman G4 Radiofrequency Generator is used with separately approved Cosman Radiofrequency Probes.

Prescription Use 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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Neil R. Dylka, M.D.
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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