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510(k) Summary

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

Contact Person: Louis Falcone, Director of RA

Registration Number: 3004867882

Date Prepared: July 11, 2008

Trade Names: Cosman RF Injection Electrodes

Common Name: Radiofrequency Lesion Probe

Classification: CFR 882.4725, Radiofrequency Lesion Probe
Class II Neurology Devices, Product Code: GXI

Predicate Devices: Technomed Europe RF Injection Needles(K042375)
Cosman Medical TC Electrodes (K050084)
Cosman Medical RF Cannula (K060799)

Device Description: The Cosman RF Injection Electrodes are used in conjunction with the commercially available Cosman RF Generator (K050084) to create radiofrequency (RF) lesions of nerve tissue or for use in percutaneous nerve blocks.. The COSMAN CU, CUR, TCD and CCD are temperature sensing RF injection electrodes. The COSMAN CP, CR and CN are non-temperature sensing RF injection electrodes. The Cosman RF Injection Electrodes are available in a variety of lengths and gauges. The Cosman RF Injection Electrodes are provided sterile packed, and are labeled for Single Use Only.

Intended Use: The Cosman RF Injection Electrodes are used for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. The nerve is localized either by electrical stimulation or by injecting contrast medium through the device and using radiography concomitantly. The nerve may then be blocked by injection of local anesthetic solution or a radiofrequency lesion is made.

Comparison to Predicate:
The Cosman RF Injection Electrodes have been compared to previously 510(k) cleared devices with respect to intended use and technological characteristics. The Cosman RF Injection Electrodes have similar physical and technical characteristics to the predicate devices. The comparison and testing results in this 510(k) notification show that the Cosman RF Injection Electrodes are substantially equivalent to predicate devices and are safe and effective for its intended use.

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Safety and Effectiveness: The comparison to the predicate device demonstrates that the Cosman RF Injection Electrodes are safe and effective and are substantially equivalent to the predicate device.

Submitted By: Name: Louis Falcone

Signature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 4 2008

Cosman Medical, Inc.
% Mr. Louis Falcone
Director of Regulatory Affairs
76 Cambridge Street
Burlington, Massachusetts 01803

Re: K082012
Trade/Device Name: Cosman RF Injection Electrodes
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI
Dated: September 30, 2008
Received: October 3, 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

K082012

Indications for Use

510(k) Number (if known):

Device Name: Cosman RF Injection Electrodes

Indications For Use:

" The Cosman RF Injection Electrodes are used for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. The nerve is localized either by electrical stimulation or by injecting contrast medium through the device and using radiography concomitantly. The nerve may then be blocked by injection of local anesthetic solution or a radiofrequency lesion is made. "

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

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