K053415 Page 1 of 2

510(k) Summary of Safety and Effectiveness Information

Company Information:

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
(781) 272-6561
email: marnold@cosmancompany.com
Registration No.: 3004867882

Date Prepared: April 21, 2006

Trade Name: LesionPoint Cannula

Common Name: Radiofrequency Lesion Probes

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

Predicate Devices:

Neurotherm RF Cannula (K994344)
Technomed Europe SMK Cannula (K042375)
Cosman Medical RF Cannula & TC Electrodes (K050084)
Smith & Nephew RF Cannula (K034012)
Diros Facet Rhizotomy Electrode & Cannula (K010202)

Description: The LesionPoint RF Cannula is used in conjunction with the commercially available Cosman RFG-1A Lesion Generator (K050084) to create radiofrequency (RF) heat lesions for the treatment of pain. The LesionPoint RF Cannula is a stainless steel cannula with an insulated shaft having an exposed (uninsulated) tip to deliver the RF energy to the tissue. The LesionPoint RF Cannula is provided as a sterile, single use, disposable device. The LesionPoint RF Cannula will be available in a variety of lengths and gauges. The LesionPoint RF Cannula is provided sterile packed, and is labeled for Single Use Only.

Intended Use: The LesionPoint RF Cannula is indicated for use in RF heat lesion procedures for the relief of pain.

Comparison to Predicate: The LesionPoint RF Cannula has similar physical and technical characteristics to the predicate devices.

Non-Clinical Data: Cosman Medical has done bench testing on the LesionPoint RF Cannula to confirm performance characteristics of this device.

Conclusion: The comparison to the predicate device demonstrates that the LesionPoint RF Cannula is safe and effective and is substantially equivalent to the predicate devices.

Very truly yours,

COSMAN MEDICAL, INC.

Michael Arnold

Michael A. Arnold, PhD
Director of Regulatory Affairs and Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2006

Cosman Medical, Inc.
c/o Michael A. Arnold, Ph.D.
Director of Regulatory Affairs
76 Cambridge Street
Burlington, Massachusetts 01803

Re: K053415
Trade/Device Name: LesionPoint RF Cannula
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI
Dated: April 11, 2006
Received: April 13, 2006

Dear Dr. 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.

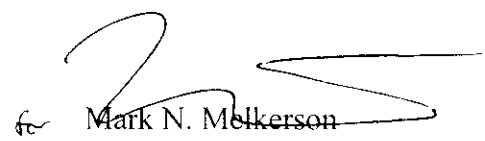
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K053415

Indications for Use

510(k) Number (if known): K053415

Device Name: LesionPoint RF Cannula

Indications For Use:

" The LesionPoint RF Cannula is indicated for use in RF heat lesion procedures for the relief of pain. "

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)
Page 1 of __1___

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

510(k) Number K053415