

K092337

6. 510(k) Summary

Submitter Information

A. Company Name: Baylis Medical Company Inc.

OCT 16 2009

B. Company Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. Company Phone: (905) 602-4875; ext 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: 27-July-2009

Device Identification

A. Device Trade Name: Pain Management Optima

B. Device Common Name: Radiofrequency Probe

C. Classification Name: Radiofrequency Lesion Probe, 21 CFR 882.4725

D. Device Class: Class II

E. Device Code: GXI

Identification of Predicate Device

Predicate device is the BMC RF Cannula, which is cleared under 510(k) Premarket Notification Number K972846

Device Description

The Pain Management Optima is a sterile, single-use cannula with an integrated probe used to deliver Radio-Frequency (RF) energy.

Intended Use

The Pain Management Optima is intended for use in Radio-Frequency (RF) heat lesion procedures for relief of pain.

Substantial Equivalence

The indications for use of the Pain Management Optima are identical to the BMC RF Cannula. Both the Optima and the Cannula are used to create radiofrequency lesions for relief of pain. The fundamental scientific technology of both these devices is also the same.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Baylis Medical Company, Inc.
c/o Mr. Meghal Khakhar
Regulatory Affairs Manager
2645 Matheson Blvd. East
Mississauga, Ontario
Canada L4W 5S4

OCT 16 2009

Re: K092337
Trade/Device Name: Pain Management Optima
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI
Dated: September 15, 2009
Received: September 24, 2009

Dear Mr. Khakhar:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092337

Device Name: Pain Management Optima

Indications For Use:

The Pain Management Optima is intended for use in radiofrequency (RF) heat lesion procedures for relief of pain

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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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Richard A. Astell
(Division Signature)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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