1. 510(k) Summary

K053082

Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2580 Matheson Blvd. E.
Mississauga, Ontario L4W 4J1
Canada

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

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: October 26, 2005

Device Identification

A. Device Trade Name: Baylis Pain Management Cooled Probe

B. Device Common Name: RF Probe

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

D. Device Class: Class II

E. Device Code: GXI

Identification of Predicate Device

Predicate device is the Baylis Pain Management Probe, which is cleared under 510(k) Premarket Notification Number K002389.

Device Description

The Baylis Pain Management Cooled Probe is a sterile, single use device that delivers Radio Frequency (RF) energy while being cooled.

Intended Use

Baylis Pain Management Cooled Probe will be used in conjunction with a Radiofrequency Generator to create radiofrequency lesions in nervous tissue.

K053082

Page 27 (2)

Substantial Equivalence

The indications for use and intended use of the Baylis Pain Management Cooled Probe are identical to the Baylis Pain Management Probe. Both the probes in conjunction with the Radio Frequency Generator are used to create radiofrequency lesions in nervous tissue. The fundamental scientific technology of both these devices is also the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2005

Meghal Khakhar, MBBS, CerRAP, RAC
Regulatory Affairs Manager
Baylis Medical Company, Inc.
2580 Matheson Boulevard E.
Mississauga, Ontario L4W 4JI
Canada

Re: K053082
Trade/Device Name: Baylis Pain Management Cooled Probe
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI
Dated: October 26, 2005
Received: November 2, 2005

Dear Dr. 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 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,

Barbara Brenner
for

Mark N. Melkerson
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): K053082

Device Name: Baylis Pain Management Cooled Probe

Indications For Use:

Baylis Pain management Cooled Probe will be used in conjunction with a Radiofrequency Generator to create radiofrequency lesions in nervous tissue.

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)

Barbara Brenner

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

510(k) Number K053082