K062937

2.0 510(k) Summary

2.1 Submitter Information

JAN - 8 2007

A. Company Name: Baylis Medical Company Inc.

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

C. Company Phone: (905) 602-4875

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: August 23, 2006

2.2 Device Identification

A. Device Trade Name: Baylis TransDiscal™ System

B. Device Common Name: TransDiscal System

C. Classification Name: Probe, Radiofrequency lesion

D. Device Class: II

E. Device Code: GXI

2.3 Identification of Predicate Device

Predicate devices are the Baylis TransDiscal™ System, which is cleared under 510(k) Premarket Notification Number K031951, and the Baylis Pain Management Cooled Probe, which is cleared under 510(k) Premarket Notification Number K053082.

2.4 Device Description

The Baylis TransDiscal System is designed to deliver controlled RF energy via two electrodes. Two TransDiscal Probes and the Pain Management Pump Unit, connected to the Baylis Pain Management Generator, work in concert to deliver the RF energy.

2.5 Intended Use

The Baylis TransDiscal System, used in combination with the Baylis Pain Management Generator, is intended for the creation of RF lesions in nervous tissue including that which is situated in intervertebral disc material.

2.6 Substantial Equivalence

This device is identical to the original Baylis TransDiscal System cleared for market release under Premarket Notification Number K031951, and is substantially equivalent to the Baylis Pain Management Cooled-Probe K053082 with respect to fundamental scientific technology. There have been no modifications to the original device. The purpose of this 510(k) application is to combine the indications of both the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Baylis Medical Company, Inc.
% Meghal Khakhar
Regulatory Affairs Manager
2580 Matheson Boulevard, East
Mississauga, Ontario L4W 4J1
Canada

JAN - 8 2007

Re: K062937
Trade/Device Name: Transdiscal System
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI
Dated: December 19, 2006
Received: December 20, 2006

Dear Meghal 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.

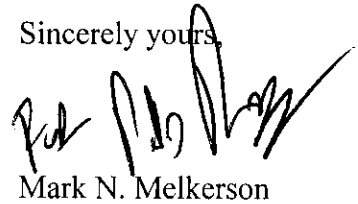
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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 (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

510(k) Number (if known): K062937

Device Name: Baylis TransDiscal System

Indications For Use:

The Baylis TransDiscal System, used in combination with the Baylis Pain Management Generator, is intended for the creation of Radio Frequency (RF) lesions in nervous tissue including that which is situated in intervertebral disc material.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
DGRND/ODE
510(k) Number K062937