K101372

6. 510(k) Summary

Submitter Information

A. Company Name: Baylis Medical Company Inc.

AUG 1 0 2010

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: 13-May-2010

Device Identification

A. Device Trade Name: DuoCool Pain Management Probe

B. Device Model Number: OSP-17-180-20 (Probe); OSK-17-180-20 (Kit)

C. Device Common Name: Radiofrequency Probe

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

E. Device Class: Class II

F. Device Code: GXI

Identification of Predicate Device

Predicate device is the Pain Management Optima, which is cleared under 510(k) Premarket Notification Number K092337

Device Description

The DuoCool Pain Management Probe is a sterile, single-use probe used to deliver Radio-Frequency (RF) energy while being cooled.

Intended Use

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

Substantial Equivalence

The indications for use of the DuoCool Pain Management Probe are identical to the Pain Management Optima. Both the DuoCool Pain Management Probe and the Pain Management Optima 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

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room-W-O66-0609
Silver Spring, MD 20993-0002

Baylis Medical Company Incorporated
% Ms. Meghal Khakhar
Regulatory and Scientific Affairs Manager
2645 Matheson Boulevard East
Mississauga, Ontario
Canada L4W 5S4

AUG 1 0 2010

Re: K101372
Trade/Device Name: DuoCool Pain Management Probe
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: Class II
Product Code: GXI
Dated: June 24, 2010
Received: June 28, 2010

Dear Ms. Kahkhar:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for 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

K101372

Indications for Use

AUG 1 0 2010

510(k) Number (if known):

Device Name: DuoCool Pain Management Probe

Indications For Use:

The DuoCool Pain Management Probe (probe model number: OSP-17-180-20; kit model number: OSK-17-180-20) is intended for use in radiofrequency (RF) heat lesion procedures for 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)

M L B Nicholas
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K101372