K122278

6.0 510(k) Summary

NOV 7 2012

Submitter Information

A. *Company Name*: Baylis Medical Company Inc.

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*: October 09, 2012

Device Identification

A. *Device Trade Name*: Baylis Medical Company Radiofrequency Perforation Generator, Model RFP-100A and optional footswitch (Model: RFA-FS)

B. *Device Common Name*: Electrosurgical Generator and optional footswitch

C. *Classification Name*: Electrosurgical Cutting and Coagulating Device
21 CFR 878.4400

D. *Device Class*: Class II

E. *Device Code*: GEI, General and Plastic Surgery

Identification of Predicate Device

- *Device*: BMC Radio Frequency Perforation Generator, Model RFP-100
  510(k) Number: K013904
  Manufacturer: Baylis Medical Company Inc.

Device Description

The Baylis Medical Company (BMC) Radiofrequency Perforation Generator is used with a compatible, separately-cleared radiofrequency (RF) device. The RF device is connected to the generator through the appropriate BMC Connector Cable, and delivers power in a monopolar

mode between its distal tip electrode and a commercially available external dispersive electrode. An optional footswitch (Model: RFA-FS) may be used with the generator.

Intended Use

The BMC Radiofrequency Perforation Generator is indicated for use in general surgical procedures to cut and coagulate soft tissue.

Substantial Equivalence

The indication for use and fundamental scientific technology of the current and predicate BMC Radiofrequency Perforation Generators is the same. The substantial equivalence of predicate and current generators is supported by the device similarities and the results of verification and validation testing.

The BMC Radiofrequency Perforation Generator conforms to the following standards:

Standard	Title
IEC 60601-1	Medical Electrical Equipment--Part 1: General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment--Part 1: General Requirements for Safety - Section 2: Collateral Standard--Electromagnetic Compatibility - Requirements and Tests
IEC 60601-2-2	Medical Electrical Equipment--Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment
ISO 14971	Medical Devices – Application of Risk Management to Medical Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 7, 2012

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

Re: K122278
Trade/Device Name: Baylis Medical Company Radiofrequency Perforation Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 09, 2012
Received: October 10, 2012

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. 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,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Baylis Medical Company Radiofrequency Perforation Generator

Indications for Use:

The Baylis Medical Company Radiofrequency Perforation Generator is indicated for use in general surgical procedures to cut and coagulate soft 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)

(Division Sign-Off)
Division of Surgical, Orthop.
and Restorative Devices

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