7. 510(k) Summary

Submitter Information

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

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

C. *Company Phone*: (905) 602-4875

D. *Company Facsimile*: (905) 602-5671

E. *Contact Person*: Meghal Khakhar

F. *Summary Prepared on*: 26-July-2013

AUG 3 0 2013

Device Identification

A. *Device Trade Name*: Baylis Medical RF Perforation Probe V2.0

B. *Device Common Name*: RF Perforation Probe

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

D. *Product Code*: GEI

E. *Device Class*: Class II

Identification of Legally Marketed Predicate Device

Device Name	Manufacturer	510(k)
Baylis Medical RF Perforation Probe	Baylis Medical Company Inc.	K010265

Indications for Use

The Baylis Medical RF Perforation Probe V2.0 is indicated for use to cut and/or coagulate soft tissue.

Device Description

The Baylis Medical RF Perforation Probe V2.0 is a sterile, single-use device that delivers radiofrequency power in a monopolar mode to its distal electrode. The device consists of an insulated core nitinol wire with a rounded tip. The distal active tip is uncoated to deliver radiofrequency energy. The device connects to a separately cleared Baylis Medical Company Radiofrequency Puncture Generator at its proximal end through a compatible BMC Connector Cable.

Comparison to Predicate Device

The Baylis Medical RF Perforation Probe V2.0 has the following similarities to the predicate device:

Characteristic	**Comment**
Intended Use	Identical
Indication for Use	Identical
Fundamental scientific technology	Identical
Operating Principle	Identical
Mechanism of action	Identical
Materials	Similar
Dimensions	Similar
Compatible devices and accessories	Identical
Packaging configuration	Identical
Sterility assurance level and Sterilization method	Identical

Performance Testing

To demonstrate substantial equivalence of the Baylis Medical RF Perforation Probe V2.0 to the cleared predicate device, the following verification tests were performed: biocompatibility, mechanical, electrical, arc integrity, and general physical.

Conclusions

The Baylis Medical RF Perforation Probe V2.0 is determined to be substantially equivalent to the cleared predicate device with respect to intended use, principles of operation, and technological characteristics. The subject device met all requirements as specified by applicable standards and the test protocols. The differences between the subject and predicate devices do not raise any new concerns of safety or effectiveness.

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

August 30, 2013

Baylis Medical Company, Inc.
Dr. Meghal Khakhar, MBBS, CerRAP, RAC
Director, Regulatory and Scientific Affairs
2645 Matheson Boulevard, East
Mississauga, Ontario
Canada L4W 5S4

Re: K132374
Trade/Device Name: Baylis Medical RF Perforation Probe V2.0
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 26, 2013
Received: August 05, 2013

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. 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 -S

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): K132374

Device Name: Baylis Medical RF Perforation Probe V2.0

Indications For Use:

The Baylis Medical RF Perforation Probe V2.0 is indicated for use to cut and/or 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)

Joshua C. Nipper -S