K121773

SEP 21 2012

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510(k) Summary

Submission by:	Biomerics, LLC
Date Prepared:	September 19, 2012
Official Contact:	Emily Madsen Quality Manager
Type of 510(k) submission:	Traditional
Common Name:	NIMBUS Electrosurgical Cutting and Coagulation Accessory
510(k) Submitter:	Biomerics, LLC 2700 South 900 West Salt Lake City UT 84119 USA
Contact Person:	Emily Madsen Quality Manager (801) 355-2705 2700 South 900 West Salt Lake City UT 84119 USA
Preference for Confidentiality:	Continued
Classification Regulation:	882.4725
Class:	II
Panel:	Neurology
Product Code:	GXI
FDA Document Numbers:	N/A
Basis for submission:	Traditional Submission New device

Name of Device: Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode

Predicate Device:

510(k) No.	Trade Name	Manufacturer
KK972846	BMC RF Cannula	Baylis Medical Company Inc.

Device Description: The NIMBUS Electrosurgical Radiofrequency Mutitined Expandable Electrode consists of an insulated cannula with an active tip that directs RF energy into target tissues, and a pair of deployable tines which expand the volume of the ablation. It is intended, in combination with an RF generator and probe, for use in radiofrequency (RF) heat lesion procedures for relief of pain.

Indications for Use

The NIMBUS Electrosurgical Radiofrequency Multitined Expandable Electrode is intended for use in radiofrequency (RF) heat lesion procedures for relief of pain using a compatible RF Generator with rated voltage less than or equal to 850V.

Technological Characteristics Comparison

The NIMBUS Electrosurgical Radiofrequency Multitined Expandable Electrode device is substantially equivalent to the indication for use predicate device. The NIMBUS Electrosurgical Radiofrequency Mutitined Expandable Electrode and the Baylis predicate consist of an insulated cannula with an active tip that directs RF energy into target tissues. Both are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain. Both devices are of similar gauge, cannula length, useable active tip length, and female luer fitting interface. The NIMBUS and Baylis devices both demonstrate substantial equivalent lesion formation under identical RF frequency and power conditions.

Brief Summary of Performance Test Results

Comparative testing versus the predicate device included:

- Thermal Properties
- Lesion Formation Volume and Shape
- Electrical Testing of
  - High frequency dielectric strength
  - High frequency leakage current
  - Mains frequency dielectric strength
  - Connection cord bend test

The technological characteristics of the Nimbus device are substantially equivalent to those of the predicate device.

Additional testing involved the following:

- Dimensional conformance to specification and active tip characterization
- Luer/injection performance
- Needle durability and Tine Integrity
- Tine deployment
- Biocompatibility and Durability
- Label verification; packaging
- Sterilization Validation
- Shelf-life Testing

The Nimbus device passed all tests and was found equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2012

Biomerics
c/o Mark Job
Third Party Reviewer
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K121773
Trade/Device Name: Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode, Model NIM17-100-10BB
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: August 31, 2012
Received: September 4, 2012

Dear Mr. Job:

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,

for Kesia Alexander

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

Indications for Use

510(k) Number (if known):

Device Name: Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode

Indications For Use: The Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode, in combination with an RF generator and probe, are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

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Petitioner's Exhibit 1049
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