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510(k) Summary

Date Prepared: December 3, 2007

Applicant:
Ion Medical, LLC
6900 Philips Highway, Suite #41
Jacksonville, FL 32216
Phone: (904) 645-7303
Fax: (904) 645-5994

DEC 1 3 2007

Contact Person: Keith Huron

Proprietary Name: Ion Medical Bipolar Coagulation Pen

Common Name: Electrosurgical handpiece

Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI)

Device Description:
The Ion Medical Bipolar Coagulation Pen is a handheld electrosurgical device which conducts low power radiofrequency current to target tissue for the purpose of coagulation. The device is comprised of an ABS plastic handle with a stainless steel coaxial probe tip and a 2-pin style connector at the proximal end for connection with compatible bipolar radiofrequency coagulation generators and cables.

Intended Use:
The Ion Medical Bipolar Coagulation Pen is a single use instrument intended to coagulate tissue using radiofrequency electric current during general and ophthalmic surgical procedures where wet field conditions exist.

Substantial Equivalence:
The Ion Medical Bipolar Coagulation Pen is substantially equivalent in technology and intended use to the currently marketed Kirwan Bipolar Pencil Coagulator (K962678) and Mentor Wet-Field Hemostatic Eraser Bipolar Instrument (K911160) in that the device conducts low power radiofrequency current, supplied by a bipolar coagulation electrosurgical generator, to a coaxial probe tip to perform tissue coagulation to control bleeding.

Safety and Effectiveness:
Device electrical safety has been demonstrated through compliance with applicable requirements of ANSI/AAMI HF18 and IEC 60601-2-2 for dielectric integrity. Biocompatibility of all patient contact materials is demonstrated through evaluation and testing in accordance with the requirements of ISO 10993-1. The device is supplied sterile and will comply with a sterility assurance level of 10^{-6}. No new issues of safety or effectiveness are a result of this device.

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Indications for Use

510(k) Number (if known): K072911

Device Name: Bipolar Coagulation Pen

Indications for Use: The Ion Medical Bipolar Coagulation Pen is a single use instrument intended to coagulate tissue using radiofrequency electric current during general and ophthalmic surgical procedures where wet field conditions exist.

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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

ION Medical, LLC
% Mr. Keith Huron
President
6900 Phillips Highway
Suite #41
Jacksonville, Florida 32216

Re: K072911
Trade/Device Name: Bipolar Coagulation Pen
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessores
Regulatory Class: II
Product Code: GEI
Dated: October 2, 2007
Received: October 12, 2007

Dear Mr. Huron:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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): K072911

Device Name: Bipolar Coagulation Pen

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072911