K081644

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510(k) Summary of Safety and Effectiveness

1. **Sponsor Name:** ConMed Endoscopic Technologies, Inc.
129 Concord Road
Billerica, MA 01821
Telephone: 978-964-4232
FAX: 978-964-4230
Contact Individual: Karen Provencher
Sr. Regulatory Affairs Specialist

Preparation Date: March 10, 2008

2. **Device Name:** ConMed Beamer™ Argon Probe

3. **Identification of Predicate or Legally Marketed Device:**
ConMed ABC Probes for Flexible Endoscopes cleared under K990586 on May 17, 1999
ERBE Straight Fire & Side Fire Probes cleared under K013348 on October 26, 2001
Canady Plasma Probes for Flexible Endoscopy cleared under K052035 on August 31, 2005

4. **Device Description:**
The Beamer Argon Probe consists of a stainless steel wire that extends from the probe connector to the distal end of the probe. The proximal end of the stainless steel wire is soldered into the connector body. The distal end of the wire is crimped to an electrode located at the distal end of the probe. The distal end of the Beamer Argon Probe has a ceramic tip which provides a thermal insulation barrier for the tubing to prevent heat degradation during coagulation. The electrode remains recessed in the ceramic tip such that there is no tissue contact during the procedure.

There are several configurations of the Beamer Argon Probe. The probes vary in length and outside diameter to accommodate the procedure performed by the physician. The Beamer Argon Probes are provided sterile by ethylene oxide and are single use only.

5. **Intended Use:**
The Beamer™ Argon Probes are indicated for argon enhanced coagulation of tissue.

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6. **Comparison of Technological Characteristics:**
The Beamer Argon Probes are substantially equivalent to the predicate devices both in intended use, technological characteristics and materials.

7. **Performance Testing:**
Biocompatibility and bench testing have been performed to demonstrate equivalence of the Beamer Argon Probes to their predicate devices. All testing passed the predetermined performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2008

ConMed Corporation
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K081644
Trade/Device Name: Beamer™ Argon Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 28, 2008
Received: August 29, 2008

Dear Mr. Lehtonen:

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

K081644

CONMED™
ENDOSCOPIC TECHNOLOGIES

C. INDICATION FOR USE

510(k) Number (if known) _____

Device Name: Beamer™ Argon Probe

Indication for Use:

The Beamer™ Argon Probes are indicated for argon enhanced coagulation of tissue.

Prescription Use __X__ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Melkerson

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

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