DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 2, 2016

CONMED Corporation
Ms. Lisa Anderson
Regulatory Affairs Specialist
525 French Road
Utica, New York 11502

Re: K151229
Trade/Device Name: ABC D-Flex Probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 22, 2015
Received: December 24, 2015

Dear Ms. Anderson:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151229

Device Name

ABC D-Flex Probes

Indications for Use *(Describe)*

The CONMED ABC D-Flex Probes are intended for use with a CONMED ABC Generator for delivery of argon gas and electrosurgical current for non-contact ablation and hemostasis at the operative site. The ABC D-Flex Probes are indicated for use during general, urological, and gynecological laparoscopic surgical procedures when manipulated by CONMED manual laparoscopic graspers or similar manual instruments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

CONMED ABC® D-Flex Probes™

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92. CONMED Corporation is hereby submitting the 510(k) Summary for 510(k) number K151229 as of June 1, 2016.

A. Submitter

CONMED Corporation
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Registration Number: 1320894

B. Company Contact

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C. Device Name

Trade Name: CONMED ABC® D-Flex™ Probes
Common Name: ABC® Flexible Laparoscopic Probes
Classification Name: Electrosurgical cutting and coagulation device and accessories

D. Predicate Device

Laparoscopic 5mm ABC Probe, K925903
Birtcher Medical Systems acquired by CONMED Corporation
Product Code: GEI
Regulation Number: 878.440

Reference Device: CONMED ABC Flex Probes, K050161
Omniguide Laser System with FlexGuide Ultra, K140378

E. Device Description

CONMED ABC® D-Flex Probes™ are monopolar, electrosurgical devices indicated for non-contact ablation and hemostasis of the operative site in laparoscopic surgery. The CONMED ABC® D-Flex Probes™ are composed of a catheter tube, ceramic tip, the D-

Flex attachment, insufflation seal, and a shrink tube. The CONMED ABC® D-Flex Probes™ are provided sterile for single use only and are controlled by the appropriate ABC® footswitch used in conjunction with compatible CONMED ABC generators.

The ABC® D-Flex Probes™ are intended for use with a CONMED ABC® Generator for delivery of argon gas and electrosurgical current for non-contact ablation and hemostasis at the operative site. The probes should be used with a maximum output of 6.5kV at a power setting of 80W.

The Laparoscopic 5mm Argon Beam Coagulation (ABC) Probe is intended to be used through a 5 millimeter (mm) laparoscopic trocar sleeve for coagulation and tissue desiccation only: this device will not cut or dissect tissue. The Laparoscopic ABC Probe is indicated for use only in situations where you would normally use monopolar energy.

Both the proposed and predicate devices are equivalent in their intended use for non-contact ablation and hemostasis, and utilize the same method of access via a cannula to the surgical site.

F. Intended Use of Device / Indications for Use

The ABC® D-Flex Probes are intended for use with a CONMED ABC® Generator for delivery of argon gas and electrosurgical current for non-contact ablation and hemostasis at the operative site. The ABC® D-Flex Probes are indicated for use during general, urological, and gynecological laparoscopic surgical procedures when manipulated by CONMED manual laparoscopic graspers or similar manual instruments.

H. Technological Characteristics

The proposed devices are equivalent to the predicate devices in their technological characteristics and performance. Both are designed for use with electrosurgical generators with ABC and monopolar high frequency current.

Both devices are designed to be activated using a foot control and to be used thru a laparoscopic cannula. However, the ABC D-Flex Probes are designed to be held by manual laparoscopic instruments compared to the Laparoscopic 5mm ABC probes which are hand-held devices.

I. Performance Data

Both devices are designed to comply with AAMI / ANSI ES60601-1:2005/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, IEC 60601-2-2:2009, and ANSI/AAMI ST67:2011. Materials analysis demonstrates the ABC® D-Flex Probe™ materials comply with the requirements of ANSI/AAMI/ISO 10993-1:2009 Biological Evaluation of Medical Devices Evaluation and Testing within a Risk Management Process. Benchtop

verification testing included grasping, release, manipulation, axial pull force, and argon flow. Functionality testing included beam initiation, non-contact ablation, and reliability. Ex-vivo comparison testing included an assessment of thermal spread depth at comparable power settings. The test results demonstrate the ABC® D-Flex Probes™ are safe and effective for their intended use and are substantially equivalent to the predicate devices.

J. Substantial Equivalence

The differences between the predicate device and the proposed device do not raise any new issues of safety or efficacy. Supporting documentation per this premarket submission confirms that ABC® D-Flex Probes™ are substantially equivalent in design, manufacturing materials, intended use, principals of operation, and technical characteristics to the Laparoscopic 5mm ABC Probes.