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

January 24, 2017

Covidien LLC
Rachel Silva
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K162802
Trade/Device Name: Barrx Anorectal RFA Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 9, 2016
Received: December 12, 2016

Dear Rachel Silva,

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K162802

Device Name
Barrx™ Anorectal RFA Wand

Indications for Use *(Describe)*
The Barrx™ Anorectal RFA Wand is indicated for use in the coagulation of bleeding and non-bleeding sites in the anal canal and rectum including, but not limited to, arteriovenous malformations, angiomata, angiodysplasia, radiation proctitis (RP), and anal intraepithelial neoplasia (AIN).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5 510(k) SUMMARY

Submitter's Name and Address:
Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact Person:
Rachel Silva
Senior Regulatory Affairs Specialist
Phone: (408) 328-7359
Fax: (408) 328-7359

Date Prepared: October 3, 2016

Name of Device:
Proprietary Name: Barrx™ Anorectal RFA Wand
Common/Usual Name: Electrosurgical Coagulation Catheter
Classification Panel: General & Plastic Surgery
Device Regulation: 21 CFR 878.4400, Class II
Product Code: GEI

Establishment Registration Number, Owner/Operator Number:
Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497

Predicate Devices:
K150251 Barrx™ Anorectal RFA Wand by Covidien
K112454 Barrx™ 60 RFA Focal Catheter by Covidien

Reason for 510(k) Submission
The purpose of this submission is to include a specific indication for use, which is Anal Intraepithelial Neoplasia (AIN), and include clinical information in the labeling resulting from three AIN related clinical studies. The intent of this 510(k) submission aligns with information stated in the FDA Guidance document titled "Guidance for Industry: General/Specific Intended Use" dated November 4, 1998 as AIN is a specific type of tissue which has been treated by the clinical community under the generic indications for use of coagulating bleeding and non-bleeding sites within the gastrointestinal tract. Also, AIN is found within a narrow target population that falls within the broader population for the products intended use.

Device Description:
The Barrx™ Anorectal RFA Wand is a sterile, single-use, bipolar device used to deliver radiofrequency (RF) energy to treatment tissue in the anal canal and rectum. The Barrx™ Anorectal RFA Wand consists of a cap with electrode, EEPROM, a proximal shaft and a rigid distal shaft with handle. The device is used exclusively in connection with the Barrx™ Flex RFA

Energy Generator (K092487). Once the device is connected, the EEPROM is read by the generator, recognizes the device, and determines the operation parameters.

Indications for Use:
The Barrx™ Anorectal RFA Wand is indicated for use in the coagulation of bleeding and non-bleeding sites in the anal canal and rectum including, but not limited to, arteriovenous malformations, angiomata, angiodysplasia, radiation proctitis (RP), and anal intraepithelial neoplasia (AIN).

The Indication for Use statement for the subject device, Barrx™ Anorectal RFA Wand is not identical to the predicate device, however the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both, the subject and the predicate devices have the same intended use for the ablation of soft tissue using RF energy.

Technological Characteristics of the Device Compared to Predicate Device
The Barrx™ Anorectal RFA Wand has identical technological characteristics to the predicate device cleared under K150251 as well as the secondary predicate device cleared under K112454. There have been minor changes to the Barrx™ Anorectal RFA Wand that did not require a submission and were documented in a letter to file.

Performance Data
The Barrx™ Anorectal RFA Wand subject device is technologically identical to the predicate device cleared under K150251 and reference predicate cleared under K112454. Accordingly, no performance testing was conducted.

Conclusion
Clinical studies referenced within this submission demonstrate the Barrx™ Anorectal RFA Wand may be used for anal intraepithelial neoplasia and is substantially equivalent to the primary predicate and reference predicate devices.