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

October 1, 2014

Covidien LLC
Ms. Rachel Silva
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K142364
Trade/Device Name: Barrx™ RFA Self Sizing Balloon Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 22, 2014
Received: August 25, 2014

Dear Ms. 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" (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 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,

Binita S. Ashar -S
2014.10.01 12:40:33 -04'00'

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142364

Device Name
Barrx™ RFA Self Sizing Balloon Catheter

Indications for Use *(Describe)*
The Barrx™ RFA Self Sizing Balloon Catheter is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including, but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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5.0 510(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: August 22, 2014

Name of Device:
Proprietary Name: Barrx™ RFA Self Sizing Balloon Catheter
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 Device(s):
K083711 Barrx™ 360 RFA Balloon Catheter by Covidien, Formerly BÂRRX MEDICAL, Inc.
K093855 Barrx™ 360 Soft Sizing Balloon by Covidien, Formerly BÂRRX MEDICAL, Inc.

Device Description:
The Barrx™ RFA Self Sizing Balloon Catheter is a sterile, single-use device that delivers radiofrequency (RF) energy to the treatment tissue within the gastrointestinal tract. The catheter is used exclusively with the Barrx™ Flex RFA Energy Generator. The Barrx™ RFA Self Sizing Balloon Catheter design incorporates the functionality of the Barrx™ 360 RFA Balloon Catheter and the Barrx™ 360 Soft Sizing Balloon into a single device. The Barrx™ 360 Soft Sizing Balloon is used to size the esophageal diameter and assist the physician in determining the size of Barrx™ 360 RFA Balloon Catheter for ablation. The Barrx™ RFA Self Sizing Balloon Catheter design enables the device to fit the esophageal diameter and ablate tissue.

Indications for Use:
The Barrx™ RFA Self Sizing Balloon Catheter is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Technological Characteristics of the Device Compared to Predicate Device
The Barrx™ RFA Self Sizing Balloon Catheter has the same technological characteristics as the predicate device; Barrx™ 360 RFA Balloon Catheter. Both devices are sterile, single use, circumferential catheters that have handles containing Electrically Erasable Programmable Read-Only Memories (EEPROMs) for connecting to the Barrx™ Flex RFA Energy Generator. Both devices have similar construction, materials, energy type, packaging, and principles of operation.

Principles of Operation
The Barrx™ RFA Self Sizing Balloon Catheter is used in connection with the Barrx™ Flex RFA Energy Generator. Once the catheter is connected, the EEPROM is read by the generator, recognizes the catheter type, and determines the operation parameters. The generator inflates air to a set pressure range. Once the pressure range has been reached, the user can initiate radiofrequency (RF) energy. Upon completion of energy delivery, the balloon automatically deflates.

The Barrx™ RFA Self Sizing Balloon Catheter has the same principle of operation as the Barrx™ 360 RFA Balloon Catheter predicate device. Both devices have an electrode attached to a balloon, use RF energy, and achieve same ablation depths. Both devices are used with the Barrx™ Flex RFA Energy Generator where the energy and power density settings are similar. Operation parameters for each device are stored in the device EEPROM connector.

Performance Data
Performance testing for the Barrx™ RFA Self Sizing Balloon Catheter consisted of in-vitro functional testing, biocompatibility testing, sterilization assessment, packaging validation, shelf life testing, electrical safety testing, and user validation. Results of performance testing demonstrate performance equivalence for the Barrx™ RFA Self Sizing Balloon Catheter when evaluated against the predicate devices.

Conclusion
Covidien llc considers the Barrx™ RFA Self Sizing Balloon Catheter to be substantially equivalent to legally marketed predicate devices Barrx™ 360 RFA Balloon Catheter (K083711) and Barrx™ 360 Soft Sizing Balloon (K093855). Test results and compliance to applicable standards provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.