January 18, 2018

Covidien llc
Saket Bhatt
Regulatory Affairs Manager
15 Hampshire Street
Mansfield, MA 02048

Re: K173559
Trade/Device Name: Barrx™ SB RFA Endoscopic Catheter
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS, GEI
Dated: December 20, 2017
Received: December 21, 2017

Dear Saket Bhatt:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173559

Device Name
Barrx™ SB RFA Endoscopic Catheter

Indications for Use *(Describe)*

Barrx™ SB RFA Endoscopic 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, Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP).

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.

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SECTION 5: 510(K) SUMMARY

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

Contact Person:
Saket Bhatt
Regulatory Affairs Manager
Phone: (408) 328-7357
Fax: (408) 328-7357

Date Prepared: November 14, 2017

Name of Device:
Proprietary Name: Barrx™ SB RFA Endoscopic Catheter
Common/Usual Name: Electrosurgical Coagulation Catheter
Classification Name: Endoscopic electrosurgical unit and accessories
Device Regulation: 21 CFR 876.4300, Class II
Product Code: KNS, GEI

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

Predicate Device(s):
K130623 Barrx™ Channel RFA Endoscopic Catheter

Device Description:
The Barrx™ SB RFA Endoscopic Catheter is a sterile, single use, focal ablation catheter used to deliver radiofrequency (RF) energy to treatment tissue within the gastrointestinal tract.

The design of the Barrx™ SB RFA Endoscopic Catheter is a modification to the legally marketed Barrx™ Channel RFA Endoscopic Catheter (cleared under K130623 on 7/26/13). The Barrx™ SB RFA Endoscopic Catheter incorporates design modifications which enable the catheter to access the small bowel within the gastrointestinal tract. The Barrx™ SB RFA Endoscopic Catheter is used in connection with the Barrx™ Flex RFA Energy Generator (cleared under K160360 on 4/5/16) which includes an output cable and footswitch.

Indications for Use:
Barrx™ SB RFA Endoscopic 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,Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP).

Technological Characteristics of the Device Compared to Predicate Device
The Barrx™ SB RFA Endoscopic Catheter incorporates design modifications which enable the catheter to access the small bowel within the gastrointestinal tract. The Barrx™ SB RFA Endoscopic Catheter design includes a longer distal torque shaft and a smaller electrode footprint. In addition to the design modifications, Barrx™ SB RFA Endoscopic Catheter utilizes a new packaging and is labeled with 3 years shelf life.

Besides the differences mentioned above, the Barrx™ SB RFA Endoscopic Catheter has same technological characteristics as the predicate device. Both devices are sterile, single use, focal ablation catheters used to deliver RF energy to treatment tissue within the gastrointestinal tract. Both devices have similar construction, materials, energy type, and principles of operation. Both devices are used in connection with the Barrx™ Flex RFA Energy Generator (K160360).

Principles of Operation
The Barrx™ SB RFA Endoscopic Catheter follows the same principle of operation as the predicate device, Barrx™ Channel RFA Endoscopic Catheter (K130623). Both devices are introduced into the gastro-intestinal tract through the working channel of the endoscope. After passing through the endoscope, both devices are directed to the targeted gastrointestinal tissue by rotating the distal torque shaft and/or the endoscope and then energy is delivered under direct visualization. Both catheters are used in connection with the Barrx™ Flex RFA Energy Generator (K160360). Once the catheter is connected, the EEPROM is read by the generator, recognizes the catheter type, and determines the operation parameters.

Performance Data
Verification and Validation activities were performed as a result of the risk analysis assessment. Performance testing consisted of in-vitro functional testing, in-vivo animal testing, biocompatibility testing, sterilization assessment, packaging validation, shelf life testing, electrical safety testing, and design and user validation. Results of performance testing demonstrate performance equivalence for the Barrx™ SB RFA Endoscopic Catheter when evaluated against the predicate device.

Conclusion
Covidien llc considers the Barrx™ SB RFA Endoscopic Catheter to be substantially equivalent to the legally marketed Barrx™ Channel RFA Endoscopic Catheter (K130623). The Barrx™ SB RFA Endoscopic Catheter has identical indications for use and principle of operation as the predicate device. The differences in characteristics do not raise new questions of safety and effectiveness as demonstrated through verification and validation activities. Test results and compliance to applicable standards provide assurance that the Barrx™ SB RFA Endoscopic Catheter has been designed and tested to meet the requirements for its indicated use.