510(k) Summary

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
Phone: (408) 328-7342
Facsimile: (408) 328-7342 (same as phone#)
Contact: Richelle Hover
Date Prepared: March 7, 2013

JUL 26 2013

NAME OF SUBJECT DEVICE AND NAME

Barrx™ Channel RFA Endoscopic Catheter

ESTABLISHMENT REGISTRATION NUMBER/OWNER OPERATOR NUMBER

Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497

Legal Manufacturer:
Covidien, llc
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:
Covidien, Formerly BÂRRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

COMMON OR USUAL NAME

Electrosurgical Coagulation Catheter

REGULATION DESCRIPTION

Classification: Class II, 21 CFR 876.4300
Product Code: GEI, KNS

PREDICATE DEVICES

HALO^{60} Catheter cleared under 510(k) K112454
HALO^{90} Catheter cleared under 510(k) K093008

DEVICE DESCRIPTION

The subject device, the Barrx™ Channel RFA Endoscopic Catheter is a sterile single-use bipolar device that delivers radiofrequency (RF) energy to the treatment tissue within the gastrointestinal tract through a copper electrode. The catheter is used exclusively with the HALO^{FLEX} Energy Generator (cleared under 510(k) K092487).

INDICATION FOR USE

The Barrx™ Channel 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 DEVICE COMAPRED TO PREDICATE DEVICE

The Barrx™ Channel RFA Endoscopic Catheter, the HALO^{60}catheter, and the HALO^{90} catheter have similar technological characteristics. All catheters are single-use, have similar construction, similar principles of operation, control mechanism, similar materials, same packaging, and the same energy type.

The main difference between the Barrx™ Channel RFA Endoscopic Catheter and the HALO^{60} and HALO^{90} catheters is the channel through which the catheter is delivered. The HALO^{60} and HALO^{90} catheters are delivered to the target tissue by mounting the device to the endoscope, whereas the Barrx™ Channel RFA Endoscopic Catheter is delivered through an endoscope. The Barrx™ Channel RFA Endoscopic Catheter is compatible with the Flex RFA Energy Generator only (K092487). The HALO^{FLEX} Energy Generator will be brand marketed as Flex RFA Energy Generator. No software change has been made to the Flex RFA Energy Generator in order to accommodate the Barrx™ Channel RFA Endoscopic Catheter.

PRINCIPLES OF OPERATION

The Barrx™ Channel RFA Endoscopic Catheter follows the same principles of operation as compared to the predicates HALO^{60} (K112454) and HALO^{90} catheters (K093008). The Barrx™ Channel RFA Endoscopic Catheter is connected to the Flex RFA Energy Generator using an output cable. Once connected, the Generator will recognize the catheter based on a unique identification in the plug and set the appropriate power density and energy density range.

The Barrx™ Channel RFA Endoscopic Catheter is introduced into the esophagus through the working channel of an endoscope. Once the targeted treatment area is identified, the catheter electrode is positioned against the tissue by deflecting the endoscope. The energy activation is performed by depressing either a front panel switch on the generator or the foot-pedal. After the energy is delivered, the coagulation effect can be verified.

SUMMARY OF TESTING PERFORMED

Verification and validation activity for the Barrx™ Channel RFA Endoscopic Catheter consisted of bench testing, biocompatibility testing, sterilization validation, packaging validation, shelf life testing, EMC and electrical safety testing, and user validation. Bench testing for the Barrx™ Channel RFA Endoscopic Catheter consisted of the following tests: (1) catheter length testing (2) shaft revolution testing (3) endoscope articulation testing (4) push force testing (5) retraction force testing (6) electrode deflection force testing (7) torque force and stability testing (8) bend radius testing (9) electrical insulation testing (10) apposition testing (11) simulated use testing (12) esophageal damage test (13) tensile force test.

CONCLUSION

Covidien, llc considers the Barrx™ Channel RFA Endoscopic Catheter to be substantially equivalent to legally marketed predicates: HALO^{60} Catheter cleared under 510(k) K112454 and HALO^{90} catheters cleared under 510(k) K093008.

The test results and compliance with applicable standards provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

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

July 26, 2013

Covidien, LLC
% Richelle Hover
Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K130623
Trade/Device Name: Barrx™ Channel RFA Endoscopic Catheter; Models TTS-1100 and TTS-1500
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS, GEI
Dated: June 20, 2013
Received: June 21, 2013

Dear Richelle Hover,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Indications for Use Statement

510(k) Number (if known): K130623

Device Name:

- Barrx™ Channel RFA Endoscopic Catheter; Models TTS-1100 and TTS-1500

Indications for Use:

The Barrx™ Channel 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).

Prescription Use _X_ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130623