K120431

510(K) SUMMARY OF SAFETY & EFFECTIVENESS
BÂRRX's HALO^{90} ULTRA Ablation Catheter

MAY - 3 2012

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

BÂRRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085
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Contact: Dawn Chang, Regulatory Affairs Manager
Date Prepared: February 10, 2012

NAME OF SUBJECT DEVICE AND NAME/ADDRESS OF SPONSOR

HALO^{90} ULTRA Ablation Catheter (model 90-9200)
BÂRRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

ESTABLISHMENT REGISTRATION NUMBER

3004904811

COMMON OR USUAL NAME

Electrosurgical Coagulation Catheter

REGULATION DESCRIPTION

Electrosurgical Cutting and Coagulation Devices and Accessories (21 CFR 878.4400, Product Code GEI)

PREDICATE DEVICE

Primary predicate device:

- HALO^{90} ULTRA Ablation Catheter (model 90-9200, cleared under K101111), hereafter referred to as "original ULTRA".

Secondary predicate device:

- HALO^{60} Ablation Catheter (model 90-9300, cleared under K112545), hereafter referred to as "HALO^{60}".

DEVICE DESCRIPTION

The subject device, HALO^{90} ULTRA Ablation Catheter (hereafter referred to as "modified ULTRA") is a sterile single-use bipolar device that delivers radiofrequency (RF) energy to the treatment tissue within the gastrointestinal tract through a copper electrode. It is used exclusively with HALO^{FLEX} Energy Generator model 1190A-115A (cleared under K092487).

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TECHNOLOGICAL CHARACTERISTICS

The modified ULTRA is a modification of the original ULTRA. Both catheters have the same construction, principles of operation, materials and energy density. The differences between the modified ULTRA and the original ULTRA include a slight change in the manufacturing process of the endoscope mounting strap, as well as dimensional modification on the pivot mechanism components.

PRINCIPLES OF OPERATION

Same as the original ULTRA and HALO^{60}, the modified ULTRA is connected to the HALO^{FLEX} Energy Generator using an output cable. Once connected, the Generator will recognize the catheter based on a unique ID in the plug and set the appropriate power density and energy density range.

The modified ULTRA is introduced into the esophagus under endoscopic visualization. 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 endoscopically.

INDICATION FOR USE STATEMENT

The HALO^{90} ULTRA Ablation Catheter (used with the HALO^{FLEX} Energy Generator, model 1190A-115A) 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).

SUBSTANTIAL EQUIVALENCE DISCUSSION AND CONCLUSION

The modified ULTRA and the predicate devices, the original ULTRA and HALO^{60}, are identical in the intended use, principle of operations, energy type, materials, packaging and sterilization method. The minor differences in component dimension are evaluated via the following bench testing: (1) Migration; (2) Deflection; (3) Catheter Distal Integrity; (4) Detachment. No new questions of safety and effectiveness were raised. The subject and the predicate devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY - 3 2012

Ms. Dawn Chang
Regulatory Affairs Manager
BARRX Medical, Inc.
540 Oakmead Parkway
SUNNYVALE CA 94085

Re: K120431
Trade/Device Name: HALO^{90} ULTRA Ablation Catheter model 90-9200
Regulation Number: 21 CFR§ 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, KNS
Dated: February 10, 2012
Received: February 13, 2012

Dear Ms. Chang:

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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K120431

Indications for Use Statement

510(k) Number (if known): ~~To be determined~~ K120431

Device Name:

- HALO^{90} ULTRA Ablation Catheter model 90-9200

Indications for Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120431