K083711

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510(k) SUMMARY

BÂRRX Medical's HALO^{360+} Ablation Catheter

1. Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared:

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Phone: (408) 328-7302
Facsimile: (408) 328-7395

Contact Person: Viorica Filimon

Date Prepared: December 11, 2008

2. Name of device and Name/Address of Sponsor:

HALO^{360+} Ablation Catheter

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

3. Common or Usual Name(s):

Electrosurgical Coagulation System

4. Classification Name:

Product code: GEI
CFR Section: 878.4400 Electrosurgical, cutting & coagulation & accessories
Device Class: II
Classification panel: General & Plastic Surgery

5. Predicate Devices

HALO^{360}+ Coagulation Catheter model 32041-xx (K071543) manufactured by BÂRRX Medical Inc;

HALO^{90} Coagulation Catheter model 90-9100 (K062723) manufactured by BÂRRX Medical Inc;

;

6. Intended Use / Indications for Use

The HALO^{360}+ Ablation Catheter intended use is for the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract.

The HALO^{360}+ Ablation 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.

7. Technological Characteristics

The HALO^{360} System consists of the following components:

- HALO^{360} Energy Generator model 1100C-115B and 1100C-230B and accessories (output cable, and an optional footswitch).
- A single use HALO^{360} Sizing Balloon model 3441B,
- A single use HALO^{360}+ Ablation Catheter model 32041-xx with an optional accessory HALO Cap

The HALO^{360} System performance and mode of operation did not change. This 510 (k) addresses the addition of the optional accessory HALO Cap.

HALO^{360+} Coagulation Catheter

There are no changes in construction, materials, principle of operation, intended use and indications for use, for the HALO^{360+} Ablation catheter model 32041-xx when compared with the predicate device HALO^{360+} Coagulation Catheter model 32041-xx. The following changes are subject to this 510k submission:

- Based on feedback received from the physician-user, BÂRRX Medical identified the need for an optional accessory HALO Cap for the use with HALO^{360}+ Coagulation Catheter. This accessory will facilitate removal of biological debris after treatment and as result minimize the time of the procedure.
- HALO^{360+} Coagulation Catheter model 32041-xx was marketed in Europe and Canada as HALO^{360+} Ablation Catheter, under the same indications for use for tissue coagulation. For unifying the international and domestic labeling we request FDA to allow the name change for HALO^{360}+ Coagulation Catheter to HALO^{360}+ Ablation Catheter. There are no changes associated with the intended use, indication for use or the principle of operation.

HALO^{360} Energy Generator

There are no changes associated to the HALO^{360} Energy Generator.

8. Substantial Equivalence

The HALO^{360+} Ablation Catheter model 32041-XX and the predicate devices HALO^{360+} Coagulation Catheter model 32041-xx and HALO^{90} Coagulation Catheter model 90-9100 are similar in construction except:

- Inclusion on an optional HALO Cap accessory
- Name changes
    - From HALO^{360+} Coagulation Catheter to HALO^{360+} Ablation Catheter
    - From HALO^{360} Coagulation System to HALO^{360} System.

All these differences were evaluated on bench and did not raise questions regarding safety and efficacy. Thus the devices are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

BÂRRX Medical, Inc.
% Ms. Viorica Filimon
530 Oakmead Parkway
Sunnyvale, California 94085

Re: K083711
Trade/Device Name: HALO^{360+} Ablation Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 11, 2008
Received: January 12, 2009

Dear Ms. Filimon:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083711

Device Name: HALO^{360+} Ablation Catheter

Indications for Use:

The HALO^{360+} Ablation 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.

Prescription Use _X_ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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