K083737 page 1 of 2

510(k) SUMMARY

BÂRRX Medical's HALO^{90} Ablation Catheter

FEB 10 2009

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 15, 2008

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

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

6. Intended Use / Indications for Use

The HALO^{90} System (inclusive of the HALO^{90} 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^{90} System consists of the following components:

- HALO^{90} Energy Generator model 1100C-115C and 90-9100 and accessories (output cable, and an optional footswitch).
- A single use HALO^{90} Ablation Catheter model 90-9100

The HALO^{90} System performance and mode of operation did not change. This 510 (k) addresses the name change for the catheter.

HALO^{90} Ablation Catheter

There are no changes in construction, materials, principle of operation, intended use and indications for use, for the HALO^{90} Ablation catheter model 90-9100 when compared with the predicate device HALO^{90} Coagulation Catheter model 90-9100.

The following changes are subject to this 510k submission: HALO^{90} Coagulation Catheter model 90-9100 was marketed in Europe and Canada as HALO^{90} 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^{90} Coagulation Catheter to HALO^{90} Ablation Catheter. There are no changes associated with the intended use, indication for use or the principle of operation.

HALO^{90} Energy Generator

There are no changes associated to the HALO^{90} Energy Generator software, hardware and accessories.

8. Substantial Equivalence

The HALO^{90} Ablation Catheter model 90-9100 and the predicate devices HALO^{90} Coagulation Catheter model 90-9100 are identical in construction except the product name changes:

- From HALO^{90} Coagulation Catheter to HALO^{90} Ablation Catheter
- From HALO^{90} Coagulation System to HALO^{90} System.

There are no 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

Ms. Viorica Filimon
Vice President, Quality and Regulatory Affairs
BÂRRX Medical, Inc.
540 Oakmead Parkway
SUNNYVALE CA 94085

FEB 10 2009

Re: K083737
Trade/Device Name: HALO^{90} Ablation Catheter (model 90-9100)
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical, cutting &coagulation & accessories
Regulatory Class: II
Product Code: GEI
Dated: December 15, 2008
Received: January 13, 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 os 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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 Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083737

Device Name: HALO^{90} Ablation Catheter (model 90-9100)

Indications for Use:

The HALO^{90} System (inclusive of HALO^{90} 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__ 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083737