K071543

510(k) SUMMARY

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

JUN 29 2007

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: June 4, 2007

Name of device and Name/Address of Sponsor:

HALO^{360+} Coagulation Catheter

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Common or Usual Name(s):

Electrosurgical Coagulation Catheter

Classification Name:

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

Predicate Device(s)

K051168 HALO^{360} Coagulation System-BÂRRX Medical Inc.
K062225 HALO^{360} Coagulation Catheter-BÂRRX Medical Inc.

Intended Use / Indications for Use

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

The **HALO^{360+}** Coagulation 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.

Technological Characteristics

The HALO^{360} Coagulation System consists of the HALO^{360} Energy Generator with a disposable single-use **HALO^{360+}** Coagulation Catheter, a HALO^{360} Sizing Balloon, an output cable, and an optional footswitch. The HALO^{360} Coagulation System comprising catheter model 32041-XX performance and mode of operation is substantially equivalent to the already cleared HALO^{360} Coagulation System comprising catheter models 31041-XX and/or 31041-XXBR.

Substantial Equivalence

The **HALO^{360+}** Coagulation Catheter model 32041-XX and the predicate device HALO^{360} Coagulation Catheter models 31041-XXBR and 31041-XX manufactured by BÂRRX Medical Inc and Stellartech Research Co. respectively have the same intended use, indications for use, technological characteristics, and principles of operation. The technological differences between the **HALO^{360+}** Coagulation Catheter model 32041-XX and its predicates are:

1) Changes in materials for manufacturability
2) Changes in manufacturing processes

All these differences were evaluated on the bench and in the animal model 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

BARRX Medical
% Ms. Viorica Filimon
540 Oakmead Parkway
Sunnyvale, California 94085

JUN 29 2007

Re: K071543
Trade/Device Name: HALO^{360+} Coagulation Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 5, 2007
Received: June 5, 2007

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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): K071543

Device Name: **HALO**$^{360+}$ Coagulation Catheter

Indications for Use:

The **HALO**$^{360+}$ Coagulation 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 System Evaluation (ODE)

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

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