510(k) SUMMARY

BARRX's HALO^{90} System

JAN - 8 2010

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

BARRX Medical, Inc.
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Date Prepared: June 2009

Name of Device and Name/Address of Sponsor

HALO^{90} System (including HALO^{90} Ablation Catheter model 90-9100 and HALO^{90} Energy Generator model 90-9000)
BARRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Common or Usual Name

Electrosurgical Coagulation System

Classification Name

Electrosurgical Cutting or Coagulation Device

Predicate Devices

HALO^{90} Ablation Catheter model 90-9100 (K060169, K062723 and K083737)
HALO^{360} Ablation Catheter (K050168, K062225, K083711)
Stellartech Coagulation Catheter (K013139, K042909, K050831)
Microvasive Gold Probe (K970278)
Olympus Heat Probe (K982289)

Intended Use / Indications for Use

The HALO^{90} System (including HALO^{90} Ablation Catheter model 90-9100 and HALO^{90} Energy Generator model 90-9000) 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

The HALO^{90} Ablation Catheter model 90-9100 operates in conjunction with HALO^{90} Energy Generator model 90-9000. There are no changes to the HALO^{90} Ablation Catheter or HALO^{90} Energy Generator implemented since the devices were cleared by K083737, K062723 and K062441. The product is also identical in principle of operation and energy density to the treatment site with the predicate devices HALO^{360} Ablation Catheter, Stellartech Coagulation Catheter. HALO^{90} is substantially equivalent in construction with the predicate devices HALO^{360} Ablation Catheter, Stellartech Coagulation Catheter and Microvasive Gold Probe. The product is similar in performance with Olympus Heat Probe. The similarities in performance and intended use with the other predicate devices are presented in Table 2.

Performance Data

The HALO^{90} Ablation Catheter model 90-9100 is technologically identical to the cleared predicate device HALO^{90} Ablation Catheter model 90-9100 cleared by K083737 and K062723. Accordingly, no performance testing was conducted.

Clinical data was provided to FDA to support the changes in the Instructions for Use associated with the use in the coagulation of bleeding sites for the HALO^{90} Ablation Catheter for the treatment of GAVE and Radiation Proctitis. Clinical data demonstrated that, when used in accordance with those instructions, the HALO^{90} Ablation Catheter used for the treatment of GAVE and Radiation Proctitis respectively is at least as safe and effective as the cleared HALO^{90} Ablation Catheter for the treatment of bleeding sites in the gastrointestinal tract .

Substantial Equivalence

The HALO^{90} Ablation Catheter with expanded indications for use is as safe and effective as the predicate devices HALO^{90} Ablation Catheter, HALO^{360} Ablation Catheter, Microvasive Gold Probe, and Olympus Heat Probe. The HALO^{90} has the same general intended use, general indications for use, technological characteristics, and principles of operation as the predicate devices.

The HALO^{90} Ablation Catheter is currently cleared for the coagulation of bleeding sites in the gastrointestinal tract. In addition, physicians have elected to use the HALO^{90} System within its indication for use for the coagulation of bleeding sites within the gastrointestinal tract, specifically gastric antral vascular ectasia (GAVE) and radiation proctitis/proctopathy (hereafter, collectively RP). GAVE and RP are similar in that they are both confined to the mucosal layer of the gastrointestinal tract, associated with hemorrhage and treated with coagulative

therapy. In this way, they are also very much akin to the other bleeding conditions (esophageal ulcers, Mallory-Weiss tears, arteriovenous malformations, angiomata, Dieulafoy lesions, and angiodysplasia) cited as examples in the HALO^{90} System cleared indication for use.

HALO^{90} Ablation Catheter is substantially equivalent with several devices: HALO^{90} Ablation Catheter (K06169, K062723 and K083737), HALO^{360} Ablation Catheter (substantially equivalency established in K060169 and K06223), Stellartech Coagulation Catheter (substantial equivalency established in K013139, K042909, K050831), Microvasive Gold Probe (equivalency established by K013139 and K970278), and Olympus Heat Probe (K982289).

HALO^{90} Ablation Catheter included in this submission has identical indications for use with the HALO^{90} Ablation Catheter (K060169, K062723 and K083737), HALO^{360} Ablation Catheter (K050168, K062225, K083711) and Stellartech Coagulation Catheter 2.0 (K013139, K042909, K050831) with the exception of Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis(RP).

Based on the substantial equivalence established historically between HALO^{90} Ablation Catheter and the predicate devices Microvasive Gold Probe (K970278) and Olympus Heat Probe (982289) we seek the expansion of the indications for use for HALO^{90} Ablation Catheter to include the GAVE (or Watermelon Stomach) indications for use as the Microvasive Gold Probe:

Indications for use for HALO^{90} Ablation Catheter current submission:

The HALO^{90} Ablation Catheter model 90-9100 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).

Indications for use for Microvasive Gold Probe (K970278):

The Gold Probe is indicated for use in transendoscopic electrocautery of visible bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus, stomach, duodenum, and colon. The indications include peptic ulcers, Mallory-Weiss tears, Arteriovenous Malformations (AVM), Angiomata, Dieulafoy Lesions, bleeding polyp stocks, angiomata, Watermelon Stomach[(1)], Barrett's Esophagus, angiodysplasia, and esophageal tumors.

(1) **Definition**: Watermelon Stomach is the popular name for **Gastric Antral Vascular Ectasia (GAVE)** — a condition in which the *lining* of the stomach bleeds, causing it to look like the characteristic stripes of a watermelon when viewed by Endoscopy.

Indications for use for Olympus Heat Probe (K982289):

The Olympus Heat Probe Unit HPU-20 has been designed for thermal cautery with the Olympus Heat Probes.

The Olympus Heat Probe has been specifically designed to thermo-cauterize bleeding sites within the gastrointestinal tract under endoscopic observation.

The addition of Physician's Instructions recommending specific treatment settings and selection criteria for the patients (Contraindications, Warnings and

Cautions) for the treatment of bleeding sites in the gastrointestinal tract such as GAVE and RP is supported by clinical data derived from publications and case studies and does improve the device risk profile by providing guidance required for optimal use of the device. The risk profile of the cleared predicate device HALO^{90} Ablation Catheter with the indication for use of coagulation of bleeding sites in the gastrointestinal sites is identical with the risk profile of the device in the current submission HALO^{90} Ablation Catheter with the indication for use for coagulation of bleeding sites in the gastrointestinal tract such as Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP). Thus, the HALO^{90} Ablation Catheter is 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

Ms. Viorica Filimon
VP Quality/Regulatory Affairs
BARRX Medical, Inc.
540 Oakmead Parkway
SUNNYVALE CA 94085

JAN – 8 2010

Re: K093008
Trade/Device Name: HALO^{90} System (including HALO^{90} Ablation Catheter model 90-9100 and HALO^{90} Energy Generator model 90-9000)
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 8, 2009
Received: December 9, 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 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,

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): K093008

Device Name: HALO^{90} System (including HALO^{90} Ablation Catheter model 90-9100 and HALO^{90} Energy Generator model 90-9000)

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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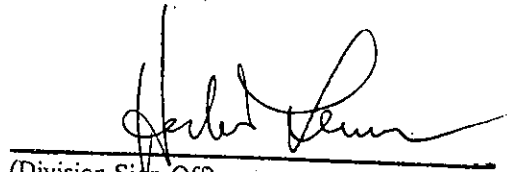
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093008