JUN 2 9 2005

K051168

# 510(k) SUMMARY

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## BARRX's HALO$^{360}$ Coagulation System

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

BARRX Medical, Inc.
1334 Bordeaux Drive
Sunnyvale, CA 94089

Phone: (408) 745-8000
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Contact: David S. Utley, M.D.

Date Prepared: May 5, 2005

### Name of Device and Name/Address of Sponsor

HALO$^{360}$ Coagulation System

BARRX Medical, Inc.
1334 Bordeaux Drive
Sunnyvale, CA 94089

### Common or Usual Name

Electrosurgical Coagulation System

### Classification Name

Electrosurgical Cutting or Coagulation Device

### Predicate Devices

Stellartech Research Corporation's Stellartech Coagulation System 2

### Intended Use / Indications for Use

The HALO$^{360}$ 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$^{360}$ consists of a Generator; a Sizing Catheter; a Coagulation Catheter; and a Catheter Connection Cable. A mains power cord and optional footswitch also are available. The HALO$^{360}$ technological characteristics and principles of operation are identical to those of the cleared Stellartech Coagulation System 2.

### Performance Data

The HALO$^{360}$ System is technologically identical to the cleared Stellartech Coagulation System. Accordingly, no performance testing was conducted. Clinical data were provided to FDA to support the Physician's Instructions contained in the Instructions for Use for the HALO$^{360}$ Coagulation Catheter. That data demonstrated that, when used in accordance with those instructions, the HALO$^{360}$ is at least as safe and effective as the Stellartech Coagulation System for the treatment of Barrett's Esophagus.

### Substantial Equivalence

The HALO$^{360}$ is as safe and effective as the Stellartech Coagulation System. The HALO$^{360}$ has the same intended use, indications for use, technological characteristics, and principles of operation as the predicate device. The addition of Physician's Instructions recommending specific power settings for the treatment of Barrett's Esophagus (a cleared indication for use of the predicate device) is supported by clinical data and does not change the device's indications for use. Thus, the HALO$^{360}$ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Barrx Medical Incorporated
C/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 13th Street, NW
Washington, District of Columbia 20004

Re: K051168
Trade/Device Name: HALO$^{360}$ Coagulation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 5, 2005
Received: May 5, 2005

Dear Mr. Kahan:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting 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): K051168

Device Name:

Indications for Use:

The HALO$^{360}$ Coagulation System 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 General, Restorative
and Neurological Devices

510(k) Number K051168