K092487

NOV 10 2009

510(k) SUMMARY

BÂRRX Medical Inc.'s HALO^{FLEX} Energy Generator

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

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Phone: 408-328-7302
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Contact Person: Viorica (Vivi) Filimon

Date Prepared: August 12, 2009

Name of Device and Name/Address of Sponsor

HALO^{FLEX} Energy Generator

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Common or Usual Name:

Electrosurgical Coagulation System

Classification Name

878.4400 Electrosurgical, cutting & coagulation & accessories, product code GEI

Predicate Devices

HALO^{360} Energy Generator model 1100C-115B	BÂRRX Medical Inc.
HALO^{90} Energy Generator model 1100C-115C	BÂRRX Medical Inc.
HALO^{90} Energy Generator model 90-9000	BÂRRX Medical Inc.
RF 3000 Radiofrequency Generator	Radio Therapeutics Corporation (Boston Scientific Inc)

Intended Use / Indications for Use

The HALO^{FLEX} Energy Generator is indicated for use for the coagulation of soft tissue

The HALO^{FLEX} Energy Generator intended use is for coagulation of soft tissue, and bleeding on non bleeding sites in the gastrointestinal tract.

The HALO^{FLEX} Energy Generator 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^{FLEX} Energy Generator is a modification to the HALO^{360} Energy Generator and HALO^{90} Energy Generators that have already been cleared by the Food and Drug Administration ("FDA" or the "Agency") for use in coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus (K051168 and K060169, K062441 respectively). The Generator has the same intended use and fundamental scientific technology as the cleared HALO^{360} and HALO^{90} Energy Generators. In addition, the intended use was expanded to include "coagulation of soft tissue", for this indication for use the predicate device is the RF 3000 Radiofrequency Generator (K000241).

The design changes between the HALO^{360} and HALO^{90} Energy Generators and the HALO^{FLEX} Energy Generator do not affect the clinical parameters employed in the energy delivery or the safety mechanisms that control those parameters.

The HALO^{FLEX} Energy Generator has a limited number of design changes compared to the predicate devices. These changes are minor and do not raise no questions or effectiveness. Further, bench testing demonstrated comparable performance and safety. These modifications were as follows:

- Add to the indications for use the "coagulation of soft tissue", to reflect the general nature of the device.
- Modification of the CPU board, for increased memory
- Consolidation of the Pressure Monitoring Board and RF MUX Board in the Hand Piece Interface Board

- Integration on the HALO^{360} and HALO^{90} Energy Generators on the same hardware platform as HALO^{360} Energy Generator
- Update the software codes to reflect the specific performance characteristics for each Energy Generator.
- Optimization of components for reliability, and/or obsolescence

Performance Data

The HALO^{FLEX} Energy Generator is technologically equivalent and clinically identical to the cleared HALO^{360} and HALO^{90} Energy Generators.

Performance testing was conducted in compliance with the applicable international and domestic requirements and the certifications (for harmonized standards) and the reports for performance testing were provided to FDA to support this submission. That data demonstrated that, when used in accordance with the instructions, the HALO^{FLEX} is at least as safe and effective as the predicate devices HALO^{360} and HALO^{90} Energy Generators.

Substantial Equivalence

The HALO^{FLEX} Energy Generator is as safe and effective as the HALO^{360} Energy Generator (K051168) and HALO^{90} Energy Generator (K060169 and K062441), RF 3000 Radiofrequency Generator (K000241) the predicate devices. The HALO^{FLEX} Energy Generator has the same intended uses and indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the HALO^{FLEX} Energy Generator and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the HALO^{FLEX} Energy Generator is as safe and effective as HALO^{360} Energy Generator (K051168) and HALO^{90} Energy Generator (K060169 and K062441), RF 3000 Radiofrequency Generator the predicate devices. Thus, the HALO^{FLEX} Energy Generator is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

BARRX Medical, Inc.
% Ms. Viorica Filimon
Vice President of Quality/Regulatory Affairs
540 Oakmead Parkway
Sunnyvale, California 94085

NOV 1 0 2009

Re: K092487
Trade/Device Name: HALO^{FLEX} Energy Generator Model 1190A-115A
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 12, 2009
Received: August 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 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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name:

Indications for Use:

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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)

FOR M. MELKERSON
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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