K122092

OCT 23 2012

510(k) Summary

Submitter's Information

Company: Medrange Corporation
480 Apollo Street
Suite D
Brea, CA 92821
Contact: Kuofang Huang
Phone: (714) 784 - 5202
Fax: (714) 255 - 1531
Email: kuofang@medrange.com

Device Identification

Device Classification Name: Electrosurgical cutting and coagulation device and accessories
Device Name: Electrosurgical Expansion System with accessories
Mod el Name: EES 100
Device Classification: Class II, according to regulation number 21 CFR 878.4400
Product Code: GEI

Predicate Device Information

Predicate Device1: Conmed CE 600
510(k) number: K081678
Predicate Device2: ERBE VIO APC 2
510(k) number: K024047
Predicate De vice 3: Force Argon II
510(k) number: K964636

Device Description

The E ES 100 is an expa nsion system for the el ectrosurgical unit (E SU). T he EE S 100 is not a generator. It is designed for the enhanced control of bleeding and the electrosurgical destruction of tissue in multispecialty procedures in the operating room or endoscopy suite. The EES 100 equipped with the argon module is use d in com bination with a hi gh-frequency generator a nd an electrosurgical handpiece and the users can select app ropriate operation modes: Pulse, Endo or Ar-cut mode to fulfill various argon surgical requirements.

Indication for Use

The EES 100 with Accessories is intended to deliver argon gas for argon plasma coagulation on tissue when use in conjunction with a Electrosurgical Generator and applicators or probes.

Technological Characteristics

The device consists of four major assemblies integrated into one system: Main Unit, Universal Cart, the Argon Module, Accessories. The EES 100 provides finer maneuverability and fits a variety of surgical equipments, endoscopes and instruments. The Software is equipped in the device. Dispense with setting or modification for the user. Dispense with training before using the device.

Performance Data

The Hazard Analysis of the device is in accordance with ISO 14971 Medical Application of Risk Management to Medical Devices. The performance of product has been tested and verified by users.

The Safety of General Requirement, EMC, Software, Usability and Alarm of the device are in compliance with following standards: IEC60601-1, IEC60601-1-2, IEC 60601-1-4, IEC60601-1-6, IEC60601-1-8. And the device is also in compliance with ANSI/AAMI HF18: Standard for Electrosurgical Instruments.

Conclusion

Since EES 100 has the same intended use, principles of operation, technological characteristics and functional capabilities as the predicate devices which have 510k cleared. The EES 100 with accessories represents good substantial equivalence to its predicate devices. And the EES 100 raises no new issues of safety or effectiveness.

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

OCT 23 2012

MedRange Corporation
% Mr. Kuofang Huang
Treasurer
480 Apollo Street, Suite D
Brea, California 92821

Re: K122092
Trade/Device Name: Electrosurgical Expansion System with accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 05, 2012
Received: September 11, 2012

Dear Mr. Huang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 : k122092

Device Name: Electrosurgical Expansion System with accessories
Model Name: EES 100

Indications for use:

The EES 100 with Accessories is intended to deliver argon gas for argon plasma coagulation on tissue when used in conjunction with an Electrosurgical Generator and applicators or probes.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number k122092