SECTION 2

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR. Part 808. Subpart E.Section 807.92

K102114

SUBMITTER'S INFORMATION [21CFR 807.92(a)(1)]

Company: Medrange Corporation
480 Apollo Street, Suite D Brea, CA 92821
Contact: Mr. Harry Woods
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DEVICE IDENTIFICATION [21CFR 807.92(a)(1)]

Trade Name: MB8010 electrosurgical unit
Common Name: Electrosurgical cutting and coagulation device and accessories
Device Class: Class II
Product Code: GEI

PREDICATE DEVICE INFORMATION [21CFR 807.92(a)(3)]

Predicate Device1: ConMed Excalibur Plus PC
Aspen Laboratories Inc.
510(k) number: K953007

Predicate Device2: Valley lab FX™
Valleylab, a Division of Tyco Healthcare LP
510(k) number: K944602

DEVICE DESCRIPTION [21CFR 807.92(a)(4)]

Medrange MB 8010 ESU is an electrosurgical generator with monopolar pure cut; blend cut, coagulation and bipolar coagulation functions which meet surgical demands.
Those functions are achieved by front panel selection of waveforms and power level. All selection is effected through push buttons and lamps which give the operator feedback of status. Power level for each mode is indicated by front panel digital displays which also show status of self-test and monitoring.

The final output power control is made through foot or hand switches.
Both monopolar and bipolar electrodes are provided. It is designed to comply with international safety standards.

INDICATION FOR USE [21CFR 807.92(a)(5)]

MB8010 Electrosurgical generator is indicated for monopolar cutting and coagulation and bipolar coagulation in surgical procedures and is intended to be used with monopolar handpieces and ground pad or bipolar handpieces and footswitches.

TECHNOLOGICAL CHARACTERISTICS [21CFR 807.92(a)(6)]

Medrange MB8010 ESU has the same intended use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices. The MB 8010 is similar in design and function to the predicate devices for the modes of operation and use.

PERFORMANCE DATA AND CONCLUSION [21CFR 807.92(b)]

Performance testing was performed to ensure that MB 8010 electrosurgical generator functions as intended, and meets design specifications.
MB 8010 conforms to ANSI/AAMI American National Standard for Electrosurgical Devices HF-18, IEC60601-1, IEC60601-1-2, IEC60601-1-4, IEC60601-1-8, IEC60601-2-2, risk management ISO14971

Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

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

Medrange Corporation
% Mr. Harry Woods
480 Apollo Street, Suite D
Brea, California 92821

NOV 2 2 2010

Re: K102114
Trade/Device Name: Medrange Electrosurgical Generator, model MB8010
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 30, 2010
Received: September 30, 2010

Dear Mr. Woods:

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,

For [signature] DEP Dir

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

Enclosure

SECTION 1

Indication for Use Statement

NOV 2 2 2010

510 (k) Number (if know): K102114 .
Device Name: Medrange MB 8010 Electrosurgical generator

Indications for use:
MB8010 Electrosurgical generator is indicated for monopolar cutting and coagulation and bipolar coagulation in surgical procedures and is intended to be used with monopolar handpieces and ground pad or bipolar handpieces and footswitches.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102114