September 18, 2020

Medrange Corporation
Helen Xie
RA Assistant
480 Apollo Street, Suite D.
Brea, California 92821

Re: K201224
Trade/Device Name: Electrosurgical Generator and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI,
Dated: August 19, 2020
Received: August 19, 2020

Dear Helen Xie:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201224

Device Name
8070 Electrosurgical Generator and Accessories

Indications for Use *(Describe)*
The Electrosurgical Generator 8070 is indicated for monopolar or bipolar surgery to achieve cut or coagulation for the tissue. It is intended to be used with monopolar handpiece and dispersive electrode or bipolar handpiece and footswitches.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Traditional 510(k) Submission

Section 5	
Version	1.1f
Pages	3
Date	September 16, 2020

1. Submitter Information

Company: Medrange Corporation
Address: Suite D, 480 Apollo Street, Brea CA 92821
Contact: Helen Xie
Phone: 1(909) 859 - 9055
Email: hx9055@gmail.com

2. Device Identification

Common name: Electrosurgical Generator and Accessories
Classification name: Electrosurgical, Cutting & Coagulation & Accessories
Trade name: Accsurg™ Electrosurgical Workstation and Accessories
Model: 8070
Device Class Class II
Product Code: GEI
21CFR Regulation Number: 878.4400

3. Predicate Device

Product MB 8010 Electrosurgical Unit
510(K) K102114

4. Device Description

8070 is an Electrosurgical Generator with Monopolar Pure cut, Monopolar Bland Cut, Bipolar function. 8070 consists of HF generator and accessories. The device generates HF power, which is transmitted to the tissue through the output Pencil. Operator selects the output function and power with the front panel. The indicator is used to indicate the setup status and output status of the device. The output is controlled by foot or hand switch.

5. Indication for use

The Electrosurgical Generator 8070 is indicated for monopolar or bipolar surgery to achieve cut or coagulation for the tissue. It is intended to be used with Monopolar, handpiece and dispersive electrode or bipolar handpiece and footswitches.

6. Substantial Equivalence Discussion

Technological characteristics

Device	Subject device	Predicate device
Manufacturer	Medrange Corporation	Medrange Corporation
Model	8070	MB 8010
510(k) Number	K201224	K102114
Class	II	II
Product Code	GEI	GEI
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Mechanism of Action	The device generates high Frequency current 400-600 kHz	The device generates high Frequency current 416-1050 kHz
System Voltage	100-240VAC- 50/60Hz	100-240VAC- 50/60Hz
4 Monopolar Cut Modes		
Max. Power	320 W (at 300Ω)	300 W (at 300Ω)
Max. Voltage Output	3800	2200
Crest Factor	1.5-2.5	1.8-2.5
Wave Forms	Sinusoidal constant / modulated Cut / Coag Pulse Phases	Sinusoidal constant / modulated
8 Monopolar Coagulation Modes		
Max. Power	120 W (at 500Ω)	100 W (at 500Ω)
Max. Voltage Output	5800	9000
Crest Factor	4.4-8.7	7.0
Wave Forms	Sinusoidal constant / modulated Cut / Coag Pulse Phases	Sinusoidal constant / modulated
4 Bipolar Modes		
Max. Power	240 W (at 100Ω)	50 W (at 50Ω)
Max. Voltage Output	900	280
Crest Factor	1.7-9	1.5-12.1
Wave Forms	Sinusoidal constant / modulated Pause Phases	Sinusoidal constant / modulated

7. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the 8070 and to show substantial equivalence to the predicate device (8070), Medrange completed successfully the following non-clinical performance tests:

General Safety Testing	IEC 60601-1:2005+C1+C2+A1:2012 Medical electrical equipment, Part 1 General requirements for basic safety and essential performance
EMC Safety Testing	IEC 60601-1-2:2014 (Edition 4.0) Medical electrical equipment, Part 1-2 General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances – Requirements and tests
HF Safety Testing	IEC 60601-2-2:2017 Medical electrical equipment, Part 2-2 Particular requirements for the basic safety and essential performance of high frequency - Surgical equipment and high frequency surgical accessories
Performance Testing	Applicable parts of FDA Guidance Document "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", May 2016
Usability Testing	IEC 60601-1-6:2010, AMD1:2013 Medical electrical equipment Part 1-6 General requirements for safety – Collateral Standard: Usability

8. Statement of Substantial Equivalence

The 8070 has the same intended use as the 8010, and the same technological characteristics. The non-clinical test results, such as performance data, software data, electrical safety and electromagnetic compatibility data have demonstrated the 8070 is as safe and effective as the predicate device. Therefore it is concluded, that the 8070 fulfills the requirements of a substantially equivalent device and that no new questions of safety and effectiveness were raised.