DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 28, 2017

Modern Medical Equipment Manufacturing Limited
Mr. Samson Woo
Quality Assurance Manager
35-41 Tai Lin Pai Rd., Unit F, 5th Fl. Gold King Ind. Bldg.
Kwai Chung, N.T. Hong Kong, China

Re: K163442
Trade/Device Name: Single Use Micro Electrode (Brass with gold plated shaft and Stainless Steel shaft)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 14, 2017
Received: August 3, 2017

Dear Mr. Woo:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K163442

Device Name
Single Use Micro Electrode

Indications for Use *(Describe)*
The electrode is used to cut and / or coagulate soft tissues by means of high frequency electrical current during an electrosurgical procedure

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. 510(k) Owner

Name:	Modern Medical Equipment Manufacturing Limited
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Telephone:	86 (768) 8897 8999
Fax:	86 (768) 8897 8666
Contact person:	Samson Woo
Date of preparation:	26 July, 2017

2. Device

Name of Device:	Single Use Micro Electrode
Trade or proprietary name:	Single Use Micro Electrode
Common or usual name:	Single Use Micro Electrode
Classification name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Panel:	General & Plastic Surgery
Product Code:	GEI
Class:	II

3. Device description

The Single Use Micro Electrodes are the monopolar active device which consist of a conductive electrode tip, an insulated shaft and a conductive post.

The conductive electrode tip configuration includes micro needles, scalpel blade, ball, broadbent, wire, triangle loop, diamond loop and round loop.

The conductive electrode tip is the conductive portion of the electrode which delivers high frequency current onto a soft tissue for cutting and coagulation during an electro-surgery

The insulated shaft is the mid portion of the electrode. It is insulated with non-conductive material included Polyolefin and /or PTFE Shrink Wrap, overmold, in order to prevent accidental conduction of the electrosurgical current from this point to the patient.

The conductive post is used to plug the electrode into the nozzle of an electrosurgical pencil from which it receives the electrical current. The diameter of the conductive post is available in 2.36mm and 1.6mm.

This device is used in conjunction with electrosurgical pencil, a compatible monopolar electrosurgical generator and patient grounding pad during electrosurgical procedure.

4. Intended use
The electrode is used to cut and / or coagulate soft tissues by means of high frequency electrical current during an electrosurgical procedure

5. Predicate device
Ellman's Ace-Tip Electrodes with 510(k) number K071343, and
Unimed's Needle Electrodes with 510(k) number K944265

6. Technological characteristic
The proposed Single Use Micro Electrode has equivalent construction and performance as the predicate devices. Different electrode tip configuration accommodate various procedural conditions.There are no new questions raised regarding to effectiveness and safety.

7. Substantial Equivalence
The technological characteristic in both proposed devices and predicate devices are identical. Moreover, performance testing data verified that operation result by using proposed device and predicate device shall be the same.

8. Performance Testing Data
Validation and Verification testing was performed on the device and its packaging.

Operation Tests include comparative testing was performed on porcine tissue: kidney, liver, and muscle for both Cut mode and Coagulation mode. It demonstrates that the thermal effect and tissue stickiness on the tip of electrode are no significant difference between proposed device and predicate device.

9. Safety and Biocompatibility testing data

Electrical Safety complies with
IEC60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)
IEC60601-2-2: 2009 (Fifth Ed)

The proposed device is a external device that contact tissue/bone/dentin for a limited contact duration (less than 24 hours). No biological effect resulted in below three tests

- Intracutaneous Reactivity
- In vitro Cytotoxicity
- Skin sensitization

10. Conclusion
Based on comparing technological characteristic and performance testing data, we believe that the proposed device, Single Use Micro Electrodes are substantial equivalence to predicate devices (K091672 and K944265).