June 16, 2020

Modern Medical Equipment Manufacturing, LTD.
Jerry Cheung
Assistant Regulatory Manager
Flat A, 11/F., Mai Wah Ind. Bldg., 1-7 Kwai Chung, N.T.,
Hong Kong, China

Re: K192542
Trade/Device Name: Single Use Electrosurgical pencil with non-coated and non-stick electrode (Non-sterile and sterile)

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 10, 2019
Received: May 11, 2020

Dear Jerry Cheung:

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)*
K192542

Device Name
Single Use Electrosurgical pencil with non-coated and non-stick electrode (Non-sterile and sterile)

Indications for Use *(Describe)*
The devices are used to cut and coagulate soft tissue 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.

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1. 510(k) Owner

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Contact person:	Mr. Jerry Cheung
Date of preparation:	30 July, 2019

2. Device

Name of Device:	Single Use Electrosurgical pencil with non-coated and non-stick electrode (Non-sterile and sterile)
Trade or proprietary name:	Single Use Electrosurgical pencil with non-coated and non-stick electrode;
Common or usual name:	Single Use Electrosurgical pencil with electrode
Classification name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Panel:	General & Plastic Surgery
Regulation number:	21 CFR 878.4400
Product Code:	GEI
Class:	II

3. Predicate and Reference devices

Predicate Device: Megadyne Pencil with 510(k) number K965054.
Reference Device: Megadyne E-Z Clean electrosurgical electrode with 510(k) number K081791

4. Device description

The Electrosurgical Pencil with coated and non-coated electrode is the monopolar active device which consists of a conductive electrode tip, an insulated shaft and a conductive post.

The electrosurgical pencil consists of a plastic handle, electrical cable and a plug. The switching modes are for “CUT” and “COAG” function. A socket in front of the pencil casing is used to allow the insertion of an electrode.

The electrode consists of a conductive electrode tip, an insulated shaft and a conductive post. The electrode tip may be blade, ball and needle. The electrode tip is either coated or non-coated. The diameter of the conductive post is 2.36mm.
The pencil with electrode is to be connected to a general high frequency electrosurgical generator by means of the electrical cable and is used in conjunction with a patient grounding pad during an electrosurgical procedure.

The switching method of electrosurgical pencil may be push button, rocker switch or foot switch, cable length of the electrosurgical pencil will be around 3m to 5m with 3-pins plug or 1-pin plug, the lengths of the blade, needle and ball electrode may be around 69mm to152mm, with coated or non-coated.

5. Indication for use
The devices are used to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.

6 Technological characteristics
The proposed devices have substantially equivalent construction and performance as the predicate devices.

7. Substantial Equivalence
The technological characteristics and performance testing of the subject and predicate devices are substantially equivalent. The following table shows the comparisons in more detail information among the subject device and the predicate devices.

Compared Items	Proposed Device Single use electrosurgical pencil and non-coated and non-stick electrode	Predicate Device (K965054) Megadyne Pencil	Reference Device (K081791) E-Z Clean electrosurgical electrode	Comments on difference
Intended use	The monopolar electrosurgical pencil with electrode is used to deliver high frequency current to target issue for cutting and coagulation	The monopolar electrosurgical pencil with electrode is used to conduct electrosurgical energy from electrosurgical generator to the target tissue	The monopolar electrosurgical electrode is used with pencil to conduct radio frequency current for cutting and coagulation from the electrosurgical generator to the target tissue	Same

Indication for use	To cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	To conduct radio frequency current for cutting and coagulation from the electrosurgical generator to the target tissue	To conduct radio frequency current for cutting and coagulation from the electrosurgical generator to the target tissue	Same
Regulation number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product code	GEI	GEI	GEI	Same
OTC or prescriptio n	For prescription use	For prescription use	For prescription use	Same
Energy delivery	High frequency electrical current/energy	High frequency electrical current/energy	High frequency electrical current/energy	Same
Monopolar or bipolar	Monopolar	Monopolar	Monopolar	Same
Design	Monopolar electrosurgical pencil for cutting and coagulation and with different electrode tips as blade, needle and ball	Monopolar electrosurgical pencil for cutting and coagulation and with different electrode tips as blade, needle and ball	Monopolar electrosurgical electrodes of different electrode tips as blade, needl and ball for cutting and coagulation	Same target purpose
Structure Pencil - Housing - Cable -Switching	 ABS PVC Push button, rocker switch & footcontrol	 ABS PVC Push button, rocker switch	 NA NA NA	The material used and structure among the purposed and predicate devices are very similar and do not raise safety and effectiveness issues because those were tested according to IEC test and biocompatibility requirements
Electrode -Material - Length	 -Stainless steel - 69 mm, 102mm, 152mm (blade & needle) - 69-71mm, 105-107mm, 135-137mm (ball)	 -Stainless steel -2.5”, 2.75”, 4”, 5”, 6.5”	 -Stainless steel -2.5”, 2.75”, 4”, 5”, 6.5”	Similar, those do not raise any safety issue Same

- Diameter - Insulation material - Electrode Tip Configuration - Electrode coating -Rated accessory voltage	- ~2.36mm -Polyolefin Shrink, Wrap and/or PTFE Shrink Wrap Or ABS/HIPS overmold -Blade, Needle, Ball -Teflon one coat - 4kVp, 5kVp	~2.36mm -Polyolefin Shrink, Wrap and/or PTFE Shrink Wrap -Blade, Needle, Ball Teflon coat 5kVp	~2.36mm -Polyolefin Shrink, Wrap and/or PTFE Shrink Wrap I -Blade, Needle, Ball Teflon coat 5kVp	The proposed electrode passes the required tests according to IEC60601-1 and IEC60601-2-2 so there will not any issue for safety. Same Similar, provide the similar function Similar, does not affect performance
Sterile	EO sterile	Gamma	Gamma	Same purpose, EO sterilization is validated according to *ISO 11135*
Shelf life	3 years	3 years	3 years	Same
Electrical safety	Comply with dielectric strength in with accordance IEC60601-1, IEC60601-1-2 & IEC60601-2-2	Comply with dielectric strength in with accordance IAAMI HF-18	Comply with dielectric strength in with accordance AAMI HF-18 and IEC60601-2-2.&	Same kinds of safety requirements
Biocompatibility	Comply with ISO10993	Should comply with ISO10993	Should comply with ISO10993	Meet to biocompatibility requirements so it does not raise any safety issue for biocompatibility

8. Non-clinical Performance Testing Data

Validation and Verification testing was performed on device sterility in accordance with ISO 11135:2014 and packaging.

Performance Testing included bench testing on the subject device and predicate devices by using porcine tissue: kidney, liver, muscle for both Cut mode and Coagulation mode in accordance with the Premarket Notification (510(k) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, Document issued on August 15, 2016, the evaluation of the thermal effects on the tissues and measurement of the thermal zone sizes are proved that the subject device and the predicate device are equivalent in the performance.

The safety performance of the subject device passed all the testing according to

internal requirements and international standards shown below to support the substantial equivalence of the subject device

- IEC60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007), Medica electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC60601-2-2: 2009 (Fifth Ed), 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.

- IEC60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests

- ISO10993, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Furthermore, the packaging integrity and accelerated aging test were completed on the subject device to support the proposed shelf life.

9. Conclusion

Based on comparing technological characteristic and performance testing data, the subject devices are substantially equivalent to predicate devices