October 11, 2023

Shenzhen Mecun Medical Supply Co., Ltd.
Mr. Bo Zheng
General Manager
2nd Level, 2nd Building, Fuqiang S&T Park 6 Ailian
Industrial Park,Zhugushi,Wulian Community, Longgang District
Shenzhen, Guangdong 518000
China

Re: K232460
Trade/Device Name: Disposable electrosurgical pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 15, 2023
Received: August 15, 2023

Dear Mr. Zheng:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

for

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232460

Device Name
Disposable electrosurgical pencil

Indications for Use *(Describe)*
The device is to be used in combination with a standard electrosurgical generator 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.

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

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510(k) Summary

(K232460)

This summary of 510(K) safety and effectiveness information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1. Submitter

Submitter's Name	Shenzhen Mecun Medical Supply Co., Ltd.
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Telephone	+86-755-86062204
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First Contact person	Name: Mr. Zheng Bo Title: General manager E-mail: manager@mecun.com
Second contact person	Name: Mr. James Cai Title: Regulatory manager E-mail: james@szcsqy.com
Data preparation	October 09, 2023

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Disposable electrosurgical pencil
Classification name:	Electrosurgical cutting and coagulation device and accessories
Classification:	II
Review Panel:	General & Plastic Surgery
Product Code:	GEI
Regulation Number:	878.4400

3. Predicate Device Information

Trade Name	Single use electrosurgical pencil with electrode
510(k) Number	K213786
Classification name	Electrosurgical cutting and coagulation device and accessories
Classification:	II
Review Panel:	General & Plastic Surgery
Product code	GEI

Regulation No. 878.4400

4. Device Descriptions

Disposable electrosurgical pencil uses high density and high frequency current on local tissue thermal effect, the tissue or tissue components vaporization or burst, the medical operation so as to achieve the cutting and coagulation. Therefore, it may not only replace surgical knife for a variety of surgical procedures, and obviously reduce the bleeding or no bleeding. This can significantly reduce the labor intensity of the medical staff, and also shorten the operation time, and is good for patient to recover after surgery.

Disposable electrosurgical pencil is the applied parts of high frequency electrosurgical equipment/generator, when the high-frequency generator outputs a certain waveform of high-frequency current, which passes through the electrosurgical electrode and applies to the tissue of patient for cutting or coagulation, then the residual current returns back to the high-frequency generator through a neutral electrode.

5. Intended Use/Indications for Use

Intended use: The monopolar electrosurgical pencil with electrode is used to deliver high frequency current to target tissue for cutting and coagulation.

Indication for use: The device is to be used in combination with a standard electrosurgical generator to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.

6. Comparisons of technological characteristics with the predicate device

The subject device and the predicate device are similar in intended use, compositions, functions, scientific technology, sterilization and method of operation, the following table provides a comparison summary:

Comparison item	Subject Device (K232460)	Predicate Device (K213786)	Remark
Manufacturer	Shenzhen Mecun Medical Supply Co., Ltd.	Ningbo Shun Ye Medical Company, Ltd.	
Product name	Disposable electrosurgical pencil	Single use electrosurgical pencil with electrode	
Product Code	GEI	GEI	Same
Regulation Number	878.4400	878.4400	Same
Classification	II	II	Same
Intended use	The monopolar electrosurgical pencil with electrode is used to deliver high frequency current to target tissue for cutting and coagulation.	The monopolar electrosurgical pencil with electrode is used to deliver high frequency current to target tissue for cutting and coagulation.	Same
Indications for Use	The device is to be used in combination with a standard electrosurgical generator to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	The device is to be used in combination with a standard electrosurgical generator to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	Same
Prescription or	Prescription	Prescription	Same

OTC			
Energy delivery	High frequency electrical current/energy	High frequency electrical current/energy	Same
User interface	Hand	Footswitch/Hand	Same
Structure	Electrode (with a cap), insulating sleeve, plastic handle, manual controlled buttons, cables and plug	*Pencil handpiece:* a plastic handle, electrical cable and a plug; *Electrode:* a conductive electrode tip, an insulated shaft and a conductive post	Same
Material	*Pencil:* -Housing: ABS; -Cable: PVC -Switching: ABS -Cap: PVC *Electrode:* - Stainless steel; - Coating: Teflon coat;	*Pencil:* -Housing: ABS; -Cable: PVC -Switching: ABS *Electrode:* - Stainless steel; - Coating: Teflon coat;	Same
Switching type	Push button	Push button, rocker switch & foot control;	Same (included)
Shape of electrode tip	Blade	Blade, Needle, Ball	Same (included)
Diameter of electrode tip	2.36 mm	2.36 mm	Same
Length of electrode tip	Blade: 69mm, 100mm, 150mm	Blade: 66mm, 70mm, 101mm, 152mm; Angled blade: 65mm; Needle: 72mm, 101mm, 152mm; Angled needle: 60mm, 66mm; Dermal tip: 60mm; Ball: 49mm, 50mm, 51mm, 132mm, 133mm, 134mm;	Similar (Note 1)
Rated accessory voltage	4kVp	4kVp	Same
Sterilization	EO sterile	EO sterile	Same
Shelf-life	3 years	3 years	Same
Biocompatibility	Comply with ISO10993-5, ISO10993-10 & 10993-11	Comply with ISO10993	Same
Electrical Performance and Safety	Comply with IEC60601-1, IEC60601-1-2, ISO60601-2-2	Comply with IEC60601-1, IEC60601-1-2, ISO60601-2-2	Same

Note 1:
The length of the electrode tip is different, the subject device has been tested the safety test, EMC test, and thermal effect test, the difference will not affect the safety and effectiveness of the subject device.

7. Performance data

The subject device conforms to the following standards and guidance:

7.1 Biocompatibility testing

The biocompatibility evaluation for Neutral electrode was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process,” as recognized by FDA. The subject device is contacted with patient’s breached or compromised surface during the electrosurgery operation for duration of less than 24 hours. The biocompatibility testing includes the following:

- Cytotoxicity
- Intracutaneous Reactivity
- Skin Sensitization
- Acute systemic toxicity
- Pyrogen

7.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the following standards:

- IEC 60601-1: 2005 + A1:2012 + A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 + A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests standard for EMC
- 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

7.3 Performance testing

Performance testing was conducted for the proposed device in accordance with requirements of FDA’s Guidance: Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (issued on March 9, 2020).

A study was performed to compare the penetrating thermal tissue effects of the Mecun disposable electrosurgical pencil. Tissues of porcine liver, porcine kidney and porcine muscle were used for thermal effect testing.

7.4 EO sterilization

The proposed device is also provided for sterility, sterilization validation is performed as the standard of ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

8. Conclusions

Based on device comparison information and performance data, the subject device is as safety and effectiveness as predicate device, and the differences do not raise any new issue of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.