February 16, 2024

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

Re: K231985
Trade/Device Name: Disposable Grounding Pad
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 5, 2023
Received: July 5, 2023

Dear Zheng Bo:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2024.02.16 13:44:10 -05'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Disposable Grounding Pad

Indications for Use *(Describe)*
The disposable grounding pad is an accessory for high-frequency surgery in monopolar applications. It is self-adhesive, ready-to-use, disposable, and single-patient-use.

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

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.
Contact Person	Zheng Bo
Address	2nd Level, 2nd Building, Fuqiang S&T Park, 6 Ailian Industrial Park, Zhugushi, Wulian Community, Longgang Street, Longgang District, Shenzhen City, China
Telephone	+86-755-86062204
Fax number	+86-755-86062204
E-mail	james@szcsqy.com; manager@mecun.com
Data preparation	February 10, 2024

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Disposable grounding pad
Model	MA2000-WAB
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	BOWA Neutral Electrodes
510(k) Number	K173877
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

Mecun disposable grounding pad has a cable and a neutral electrode, the electrode consists of a conductive adhesive area surrounded by a non-conductive border.

The neutral electrode is intended to be equipped with a compatible generator which has a CQM, loss of safe contact between the neutral electrode and the patient will result in an alarm.

The disposable grounding pad is a non-sterile, non-active dispersive conductor intended to be fastened to a patient and connected to a high frequency surgical equipment, to create a circuit for the return of electrical current to the generator after its emission to perform electrosurgery on the patient. It is fastened to the patient's body typically where the greatest surface area can be covered in closest proximity to the surgical site. It may or may not include a return cable(s). This medical device is intended for disposable and single-patient use.

5. Indications for Use

The disposable grounding pad is an accessory for high-frequency surgery in monopolar applications. It is self-adhesive, ready-to-use, disposable, and single-patient-use.

6. Comparisons of technological characteristics with the predicate device

The subject disposable grounding pad and BOWA neutral electrodes (K173877) are similar in intended use, compositions, functions, scientific technology, materials and method of operation, the following table provides a comparison summary:

Comparison item	Subject Device	Predicate Device (K173877)	Remark
Manufacturer	Shenzhen Mecun Medical Supply Co., Ltd.	BOWA-electronics GmbH & Co. KG	
Product name	Disposable Grounding Pad	BOWA Neutral Electrodes	
Product Code	GEI	GEI	Same
Regulation Number	878.4400	878.4400	Same
Classification	II	II	Same
Intended use& Indications for Use	The disposable grounding pad is an accessory for high-frequency surgery in monopolar applications. It is self-adhesive, ready-to-use, disposable, and single-patient-use.	Disposable neutral electrodes are self-adhesive, ready-to-use and single-use products and are an accessory for HF surgery in monopolar applications. The electrodes complete the electrical circuit between the patient and the HF generator on the passive side.	Same
Prescription or OTC	Prescription	Prescription	Same
Mechanism of Action	Neutral electrodes serve to return the current from the patient to the electrosurgical unit (ESU) during HF-surgery in Monopolar application.	Neutral electrodes serve to return the current from the patient to the electrosurgical unit (ESU) during HF-surgery in Monopolar application.	Same
Technology overview	Multi-layer device consists of: Backing material; Conductive layer;	Multi-layer device consists of: Backing material; Conductive layer;	Same

	Conductive adhesive hydrogel; Cover material	Conductive adhesive hydrogel; Cover material	
Intended population	Adult	Neonates, Children, Adults	Similar (included)
Anatomical location	Muscular or well vascularized convex skin site, as close as possible to the operating field	Muscular or well vascularized convex skin site, as close as possible to the operating field	Same
Weight range according to IEC 60601-2-2	>15kg (33lbs) Adults	>15kg (33lbs) Adults >5kg (11lbs) Children and Adults Between 5 and 15kg (11 to 33lbs) Children <5kg (11lbs) Neonates	Similar (included)
Conductive area	124 cm^2 Adults	140 cm^2 Adults 110 cm^2 Children and Adults 70 cm^2 Children 40 cm^2 Neonates	Similar (included)
Material	Conductive laminate: Al-foil/PET and medical grade hydrogel Backing: PE-foam Cover: release liner	Conductive laminate: Al-foil/PET and medical grade hydrogel Backing: PE-foam Cover: release liner	Same
Maximum power rating	124 cm^2: 400W	140 cm^2 not limited 110 cm^2 not limited 70 cm^2 limited to 200W 40 cm^2 limited to 100W	Similar (included)
Maximum current density (power setting: 400W, load: 500Ω)	6.29 mA/cm^2 (Electrode pad: 124cm^2)	5.79 mA/cm^2 (Electrode pad: 140cm^2) 6.45 mA/cm^2 (Electrode pad: 110cm^2)	Similar (included)
Maximum power density	Adult type: 3.23W/cm^2	Adult type: not limited	Similar (included)
Maximum permitted voltage for the cable	500 Vp	500 Vp	Same
Self-adhesive	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Single-use/disposable	Yes	Yes	Same
Shelf-life	2 years	3 years	Note 1
Biocompatibility	ISO10993-5, ISO10993-10	ISO10993-5, ISO10993-10	Same
Electrical Performance and Safety	IEC60601-1, IEC60601-1-2, ISO60601-2-2	IEC60601-1, IEC60601-1-2, ISO60601-2-2	Same
Compatibility with HF generators (ESU)	Yes, if ESU is equipped with a CQM system which fulfils IEC 60601-1	Yes, if ESU is equipped with a CQM system which fulfils IEC 60601-1	Same
Accessory	Provide with cable	Provide with or without cable	Similar (included)

Note 1:
The shelf-life of subject device has been validated by accelerated aging test, the difference does not raise any new safety and effectiveness issue.

7. Performance data

The subject device conforms to the following standards:

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 intact skin during the electrosurgery operation for duration of less than 24 hours. The biocompatibility testing includes the following:

- Cytotoxicity
- Intracutaneous Reactivity
- Skin Sensitization

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 of appearance and size

The appearance and size of the disposable grounding pad, 3 lots of pads and 5 pieces for each were inspected, the testing results showed the appearance and size of the proposed device met the design requirements.

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.