June 19, 2025

Baisheng Medical Co., Ltd.
Haley Lin
Registration Specialist
No.11 Fusheng Road, Xinhui District 529100
Jiangmen, Guangdong 529100
China

Re: K251235
Trade/Device Name: Electrosurgical Pads
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 22, 2025
Received: April 22, 2025

Dear Haley Lin:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.06.19 16:01:45 -04'00'

James Jang, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251235

Please provide the device trade name(s).

Electrosurgical Pads

Please provide your Indications for Use below.

Electrosurgical Pads are Neutral Electrode which is also known as plate, plate electrode, passive, return, or dispersive electrode. They are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient.
Solid Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical Pads are for use with generators that have a CQMS (i.e. REM, ARM, NESSY, etc.).

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

Electrosurgical Pads

Baisheng Medical Co., Ltd.

Date prepared: Apr. 22, 2025

510(k) submitter ADMINISTRATIVE INFORMATION

Manufacturer Name: Baisheng Medical Co., Ltd.

Address: No.11 Fusheng Road, Xinhui District 529100 Jiangmen City, Guangdong, PEOPLE'S REPUBLIC OF CHINA

General Manager: Mr. Chen Xi

E-mail: renzhen@bs0750.com

Official Contact Person: Haley Lin-Registration Specialist

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SUBJECT DEVICE NAME AND CLASSIFICATION

Trade/Device Name: Electrosurgical Pads

Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulation Number: 21 CFR 878.4400

Regulation Class: Class II

Product Code: GEI

Review Panel: General & Plastic Surgery

PREDICATE DEVICE INFORMATION

The Subject device in this submission is substantially equivalent in indications for use and design principles to the following predicate device

510(k) Number	Predicate Device	Company Name
K233615	Electrosurgical Pads	Baisheng Medical Co., Ltd.

REFERENCE DEVICES INFORMATION

510(k) Number	Predicate Device	Company Name
K160290	Valleylab REM Polyhesive Infant Patient Return Electrode	Covidien LLC
K822572	Valleylab REM Polyhesive Adult Patient Return Electrode	Covidien LLC
K861036	Valleylab REM Polyhesive Adult Cordless Patient Return Electrode	Valleylab, INC.

DEVICE DESCRIPTION

Electrosurgical Pads are single-use, non-sterile dispersive electrode with or without a pre-attached cord. This devices are used in monopolar surgery to complete the electrical circuit with the generator. Providing a low-impedance path back to the generator through the return electrode helps to prevent unintended RF burns. The Electrosurgical Pads are designed to be compatible with the return electrode monitoring function of compatible OBS generators.

INDICATIONS FOR USE

Electrosurgical Pads are Neutral Electrode which is also known as plate, plate electrode, passive, return, or dispersive electrode. They are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient.

Solid Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical Pads are for use with generators that have a CQMS (i.e. REM, ARM, NESSY, etc.).

EQUIVALENCE TO MARKETED DEVICE

The subject device is highly similar to the predicate device with respect to Indications for Use, and technological principles. The comparison tables at below comparing the indications for Use and technological characteristics of the subject and predicate/reference devices.

Indications for Use Between the Subject Device and Predicate Device

Device	Subject Device	Predicate Device	Discussion
Indications for use statement	Electrosurgical Pads are Neutral Electrode which is also known as plate, plate electrode, passive, return, or dispersive electrode. They are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit	Electrosurgical Pads are Neutral Electrode which is also known as plate, plate electrode, passive, return, or dispersive electrode. They are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit	The subject device and predicate device's indications for use are the same.

	during electrosurgery between the electrosurgical generator, the active electrode and the patient. Solid Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical Pads are for use with generators that have a CQMS (i.e. REM, ARM, NESSY, etc.).	during electrosurgery between the electrosurgical generator, the active electrode and the patient. Solid Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical Pads are for use with generators that have a CQMS (i.e. REM, ARM, NESSY, etc.).	

Indications for Use Between the Subject Device and Reference Devices

Device	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3	Discussion
Indications for use statement	Electrosurgical Pads are Neutral Electrode which is also known as plate, plate electrode, passive, return, or dispersive electrode. They are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient. Solid Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical Pads are for	The REM Polyhesive Infant Patient Return Electrode is a single use, non-sterile dispersive electrode with a preattached cord. The electrode adheres to the patient over its entire surface. Its purpose is to complete the electrosurgical circuit between the generator, the active electrode, and the patient. The product is used for general monopoloar electrosurgery on newborns, infants, and children weighing between approximately 6 and 30 lb.	The E7507 and E7507DB patient return electrodes are single use, non-sterile dispersive electrodes with a preattached cord. The electrode adheres to the patient over its entire surface. lts purpose is to complete the electrosurgical circuit between the generator,the active electrode, and the patient. These products are used for general monopolar electrosurgery on patients of approximately 30 pounds or greater.	The E7508, E7509, and E7509B patient return electrodes are single use, non-sterile dispersive electrodes intended to be used with the E0560 or E0560E patient return electrode reusable cord/clamp assemblies. The electrode adheres to the patient over its entire surface. The cord connects and clamps onto the electrode in order to complete the electrosurgical circuit between the generator, the active electrode, and the patient. These products are used for	1. The subject device and reference device's indications for use are highly similar. All are intended to complete the electrosurgical circuit between the generator, the active electrode, and the patient. 2. Only differ with the weight range and the pre-attached cord. The subject device intended for three weight range patients, with no upper body weight limit. The reference device 2 &3 are for patients weighing over 30 pounds, while reference

	use with generators that have a CQMS (i.e. REM, ARM, NESSY, etc.).			general monopolar electrosurgery on patients of approximately 30 pounds or greater.	device 1 is for patients weighing between approximately 6 and 30 lb (6 and 30pounds). 3. The reference device 1 &2 both are with a pre-attached cord, while the reference device 3 is cordless, and it need to be combination used with reusable cord/clamp.

Technological Characteristics

Parameter	Subject Device	Predicate Device (K233615)	Reference Device 1 (K160290)	Reference Device 2 (K822572)	Reference Device 3 (K861036)	Differences Discussion
Device Name	Electrosurgical Pads	Electrosurgical Pads	Valleylab REM Polyhesive Infant Patient Return Electrode	Valleylab REM Polyhesive Adult Patient Return Electrode	Valleylab REM Polyhesive Adult Cordless Patient Return Electrode	/
Product Code	GEI	GEI	GEI	GEI	GEI	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Same
Regulatory Class	Class II	Class II	Class II	Class II	Class II	Same
Technology	Conductive resin that adheres to the patient's skin and conducts electrical current away from the patient's body					Same
Model	GBS-Db4030, GBS-Db4030c, GBS-Db4030c-45 GBS-Db4030bc, GBS-Db4030nc,	See below table 6	E7510-25, E7510-25DB	E7507, E7507-DB	E7508, E7509, E7509B	/

	GBS-Dm4020, GBS-Dm4020c					
Corded or Non-corded	Corded and Non-corded	Corded and Non-corded	Corded	Corded	Non-corded	Same. The subject device include corded and non-corded, is the same as the predicate device, and the reference device 1 & 2 have cord, while the reference device 3 is cordless.
Applicable Patient Weight	<5kg: GBS-Db4030nc 5kg to 15kg: GBS-Db4030bc >15kg: GBS-Db4030, GBS-Db4030c, GBS-Db4030c-45, GBS-Dm4020, GBS-Dm4020c:	Neonates:<5kg Children:>5kg Children and Adult:>5kg, <15kg Adult:＞15kg See below table 6	6 and 30lb (2.7kg to 13.6kg)	30lb or greater (>13.6kg)	30lb or greater (>13.6kg)	Same. The subject device and predicate device both are intended for three weight range patients. But is different with the reference devices, reference devices only for single weight range patients.
Overall Dimensions	<5kg: 5.35*9.85=52.3cm2 5kg to 15kg: 9.5*12=114cm2	See below table 6	9.5x12.1cm=114.95cm2 From brochure	18.3x11.4cm=208.62cm2 From brochure	18.3x11.4cm=208.62cm2 From brochure	Highly similar. The subject device intended for three weight range population patients, so it have three sizes applicable. The predicate device

	>15kg: 18.4*11.5=211.6cm2					have fifteen sizes applicable. The reference devices only have single size respectively. Highly similar to the subject device. The pads are intended to carry current in application, the Electrical Safety & EMC tests have been conducted and conformed to standards. So the size has no influence on safety and performance.
Conductive Surface Area	<5kg:32.76cm2 5kg to 15kg:75cm2 >15kg:141.3cm2	Neonates:43cm2 Children:87cm2 Children and Adult:135-307cm2 Adult:100-144cm2 See below table 6	75cm2 From brochure	137cm2 From brochure	1373cm2 From brochure	Highly similar. Some model of the predicate device have larger surface area, but the subject device are the same as the reference devices. Comply with clauses 201.15.101.4 of IEC 60601-2-2. Test results verified the differences do not raise additional safety or effectiveness concerns.
Frame Width	<5kg:0.7cm±2cm 5kg to 15kg:1cm±2cm >15kg:1.2cm±2cm	/	0.95cm From brochure	1.11cm From brochure	1.11cm From brochure	Different. The subject device has a frame while the predicate device has no frame. But it is the same as

						reference devices, only differ with the dimension. A frame is adhered around the border to secure the gel to prevent them from unraveling, rotting, or falling off the patient's skin during operation. The difference have been evaluated through appropriate biocompatibility and performance testing and met the standards.
Patient Contact Materials	Conductive gel (Sodium Polyacrylate, Propanetriol (Glycerin), Water, Potassium Chloride)	Conductive gel (Sodium Polyacrylate, Propanetriol (Glycerin), Water, Potassium Chloride)	Conductive gel (adhesive polymer matrix, water, electrolytes, blue colorant, and preservative) Pressure-sensitive adhesive border Silicone-coated paper	Unknown	Unknown	Same as predicate device. Similar to reference devices. The difference have been evaluated through biocompatibility testing and met the standards.
Biocompatibility Properties	Comply with the standards of ISO 10993	Comply with the following standards: ISO 10993-5,	Be tested and conform to ISO 10993. Be subjected to	Unknown	Unknown	Same. All products had met the requirements.

		ISO 10993-10, ISO 10993-23	cytotoxicity, sensitization, and primary skin irritation tests.			
Safety and Performance Properties	Comply with relevant clauses of IEC 60601-2-2, IEC 60601-1, IEC 60601-1-2	Comply with the following standards: IEC 60601-1:2005, IEC 60601-2-2:2017, IEC 60601-1-2:2014	Conform to IEC 60601-1:2005, IEC 60601-2-2:2009, IEC 60601-1-2:2007 and 2014	Unknown	Unknown	Same. All the testing were conducted in accordance with latest version standards.
Shelf life	3 years	3 years	Two years	Two years	Two years	Same. But different with reference devices. The real time aging verification for subject device has been conducted and conformed to three years shelf life criteria.
Single use	Yes	Yes	Yes	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same

CLINICAL TESTING

The performance of Electrosurgical Pads in the clinical environment has been well established. No clinical data is included in this submission.

NON-CLINICAL PERFORMANCE TESTING

Performance test, Electrical safety test, Electromagnetic compatibility(EMC) test and biocompatibility test have been done to demonstrate the safety and performance of subject device. The test details as follows:

1. Performance test was performed according to:

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, and, Final Products Inspection Protocol.

2. Electrical safety test, Electromagnetic compatibility(EMC) test Compliance with

- IEC 60601-1-2: 2014/ AMD1: 2020 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests, and,
- IEC 60601-1: 2005+A1: 2012+A2: 2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

3. A biological evaluation was performed on the Subject device according to ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process

4. Biocompatibility test was performed according to:

- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, and,
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization, and,
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation.

Non-clinical performance testing of the Subject device met the acceptance criteria for each validation and test described above. This non-clinical performance testing demonstrates that the Subject device is suitable for intended use.

CONCLUSION

Since the Indications for Use statements for the subject and predicate/reference devices are highly similar, differing slightly only in structure comparing to predicate device but same as reference devices. Additionally the technological characteristics of

the subject device are the same or highly similar to the predicate device with any differences mitigated through non-clinical performance testing.
Overall, these similarities between the subject and predicate devices, support a determination of substantial equivalence.