December 23, 2024

Beijing Taktvoll Technology Co., Ltd.
Fan Dan
Vice General Manager
302 Room, 10A, Lian dong U village , Jing Sheng Nan fourth
Street, Jin Qiao Chan Ye Ji Di, Tong Zhou district
Beijing, Beijing 101102
China

RE: K240975
Trade/Device Name: Electrosurgical Generator (ES-100); Electrosurgical Generator (ES-300)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 9, 2024
Received: April 10, 2024

Dear Fan Dan:

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,

Francisco Delgado -S
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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)*
K240975

Device Name
Electrosurgical Generator

Indications for Use *(Describe)*
The Electrosurgical Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

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 - K240975

I Submitter

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Date Prepared: December 19, 2024

II Device

Trade Name of Device:	Electrosurgical Generator
Regulation Number:	21 CFR 878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	Class II
Product Code:	GEI
Review Panel:	General and Plastic Surgery

III Predicate Devices

Trade Name:	Bovie IDS-310 High Frequency Electrosurgical Generator
Common Name:	Electrosurgical Generator (ESU)
Regulation Number:	Class II, 21 CFR 878.4400
Product Code:	GEI
Premarket Notification:	K134054
Company Name:	Bovie Medical Corporation

IV Device Description

The ES-100 and ES-300 Electrosurgical Generator are advanced high-frequency surgical devices designed to provide versatility and safety in various surgical procedures. Both models offer a range of operating modes, including monopolar electrosurgical excision modes, monopolar electrocoagulation modes, and bipolar modes, catering to the diverse needs of surgeons. The maximum output power of the ES-100 is 100 W, while the ES-300 offers increased output power of up to 300 W, providing surgeons with enhanced capabilities for cutting and coagulation in various surgical procedures. Both models are equipped with

manual and foot switch controls, allowing for seamless operation during surgeries. They feature volume control for adjusting the device's audio output, memory functions for storing recent settings, and built-in return electrode monitor systems for real-time safety monitoring.

Unique Features

ES-100 Electrosurgical Generator:
The ES-100 offers three monopolar electrosurgical excision modes: pure cut, blend cut 1, and blend cut 2, along with two monopolar electrocoagulation modes: spray coagulation and forced coagulation. It also includes a standard bipolar mode for various applications and is designed for comprehensive surgical use.

ES-300 Electrosurgical Generator:
The ES-300 features four monopolar electrosurgical excision modes: pure cut, blend cut 1, blend cut 2, and blend cut 3, along with three monopolar electrocoagulation modes: spray coagulation, forced coagulation, and soft coagulation. It also includes three bipolar modes: macro mode, standard mode, and precise mode, providing versatility in bipolar applications. Additionally, the ES-300 is equipped with the TAKTVOLL REM system for enhanced safety monitoring and features a memorization function for quick access to settings during surgeries.

V Indications for Use

The Electrosurgical Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

VI Comparison of Technological Characteristics with the Predicate Device

The subject device (Electrosurgical Generator) has the same Indications for Use, and similar technological characteristics, design, and performance specifications, as the predicate device. The differences between the subject and predicate devices do not raise new or different questions of safety and effectiveness.

Device feature	Electrosurgical Generator (subject device)		Bovie IDS-310 High Frequency Electrosurgical Generator K134054 (predicate device)	Discussion
	ES-100	ES-300		
Intended Use	The Electrosurgical Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.		The Bovie IDS-310 is intended for cutting, coagulation, and bipolar coagulation of tissue in general surgery procedures.	Identical
Major Functions	Bipolar, Monopolar, Temperature Sensors, Impedance Monitor	Bipolar, Monopolar, Temperature Sensors, Impedance Monitor, Continuity Monitor	Bipolar, Monopolar, Temperature Sensors, Impedance Monitor, Continuity Monitor	Similar
Operating Modes	6 modes including cutting, blend, coagulation modes and bipolar.	10 modes including cutting, blend, coagulation modes and bipolar.	Multiple modes including cut, blend, coagulation, and bipolar functionality.	Identical
Output Frequency	416 kHz	416 kHz	350 kHz to 450 kHz 490 kHz ± 4.9 kHz	Similar
Waveforms	Various waveforms available for different modes in both devices		Various waveforms available for different modes	Similar
Power Output	Up to 100 W	Up to 300 W	Up to 300 W	Identical
Voltage Output	Up to 4800 V	Up to 4800 V	Up to 4000 V	Similar
Crest Factor	6.3	6.3	6.0 ± 20%	Similar
Modulation	Up to 25 kHz	Up to 25 kHz	30 kHz ± 5 kHz	Different

Device feature	Electrosurgical Generator (subject device)		Bovie IDS-310 High Frequency Electrosurgical Generator K134054 (predicate device)	Discussion
	ES-100	ES-300		
frequency				
Input Power	AC 100 - 240 V, 50/60 Hz 1100 VA	AC 110 V - 120 V, 60 Hz 1100 VA	100 – 240 V ± 10% 50 – 60 Hz 504 VA 6.3 A (slow blow)	Different
Physical Specifications	Compact design, touch interface, lightweight		Compact design, touch interface, lightweight	Identical
Energy Type	High Frequency (RF)		High Frequency (RF)	Identical

Discussion:

- Indications for Use: The Indications for Use of the subject device are the same as those of the predicate device.

- Technology: Both devices utilize the same technology to achieve the intended use. The main difference is in some of the performance specifications. Our performance test report provides detailed comparisons of the output power curves of ES-100 and ES-300 across various modes against the Bovie IDS-310. The key findings indicate that the output parameters of ES-100 and ES-300 in each mode meet the technical specifications, and when compared with Bovie IDS-310, the trends in output curves for each mode are consistent, demonstrating comparable output power. This evidence supports the conclusion that ES-100 and ES-300 are substantially equivalent to the Bovie IDS-310 in terms of performance.

VII Performance Data

Non-Clinical Testing

A battery of tests for electrical safety and electromagnetic compatibility was performed to verify that the proposed device met all design specification. The test result demonstrated that the proposed 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 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests
- 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

Bench testing assessed the output performance of the ES-300 and ES-100 electrosurgical units across multiple modes, focusing on waveform characteristics and power delivery. Comparisons with the predicate device confirmed consistent performance, ensuring reliability, safety and effectiveness for clinical use.

Pre-clinical test rigorously evaluated the thermal damage induced by the ES-100, ES-300, and IDS-310 electrosurgical units, comparing their performance in terms of thermal injury dimensions and edge carbonization across different tissues and settings, to ensure safety and effectiveness in clinical applications.

VIII Clinical Data

Clinical testing was not conducted to support a substantial equivalence determination.

IX Conclusion

The Electrosurgical Generator is substantially equivalent to the predicate device (Bovie IDS-310 High Frequency Electrosurgical Generator). The non-clinical testing demonstrates that the differences between the subject and predicate device do not raise new or different questions of safety and effectiveness.