December 10, 2024

Jeisys Medical Inc.
% Sanghwa Myung
Regulatory Affair Consultant
E&M
D-1474, 230, Simin-daero, Dongan-gu
Anyang-si, Gyeonggi-do 14067
South Korea

Re: K231216
Trade/Device Name: Potenza
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, OUH
Dated: December 3, 2024
Received: December 4, 2024

Dear Sanghwa Myung:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.12.10 16:07:57 -05'00'

Long Chen, PH.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K231216

Device Name
POTENZA

Indications for Use *(Describe)*
The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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

K231216

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

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Date 510(k) summary prepared: December 10, 2024

1. DEVICE

Name of Device: POTENZA

Common or Usual Name: Electrosurgical coagulation device and accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR Part 878.4400)

Regulatory Class: II

Product Code: GEI, OUH

2. PREDICATE DEVICE

Jeisys Medical, Inc.
878.4400 / GEI
K201685, POTENZA

Note: the POTENZA has not been subject to a design-related recall, removal or correction.

3. DEVICE DESCRIPTION

The POTENZA is an RF (radiofrequency), software-controlled electrosurgical device used for electrocoagulation of soft tissue and hemostasis.

The POTENZA generates radiofrequency (RF) energy by means of high RF at 1MHz or 2MHz. The RF energy is delivered through the skin into the target tissue via a handpiece equipped with an electrode tip. As the RF energy passes through the tissue, it generates an electrothermal reaction which is capable of coagulating the tissue.

The POTENZA has two operating modes: monopolar mode and bipolar mode. In the monopolar mode, RF energy flows from the main unit and a patient loop is formed by pairing the active electrode tip with the neutral electrode pad. Heat is not generated in the neutral electrode pad due to its low contact resistance, but heat is generated in the active electrode tip which has higher contact resistance. The higher contact resistance heats up the tissue resulting in coagulation. In the bipolar mode, RF energy is delivered between adjacent needles in the electrode tip without use of the neutral electrode pad. The user can select the mode and adjust parameters through the touch screen user interface of the electrosurgical device.

The clinical use model for the POTENZA is identical to that of comparable electrosurgical devices, intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

4. INDICATIONS FOR USE

The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

5. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The ***subject device,*** POTENZA, is identical to the ***predicate device,*** POTENZA, cleared under K201685 except for the following changes described in below.

- Addition of Three electrode tips for the motor handpiece: CP-16 TIP and CP-25 TIP, CP-49 for monopolar and bipolar operating modes
- Labeling changes to add the new tips; refer to Section 14. Proposed Labeling

The NEW POTENZA consists of the following components:

- Electrosurgical Unit - Main body
- handpieces

-> electrode tips for the handpiece – Add three invasive tips

- Neutral electrode pad and neutral electrode pad cable, cleared under K201685
- Handpiece stand
- Foot switch

- Power cord

	Subject	***Predicate***	Substantial Equivalence
Manufacturer	Jeisys Medical, Inc.	Jeisys Medical, Inc.	-
Regulation Number / Product Code	878.4400 / GEI	878.4400 / GEI	-
510(k) Number(s)	Pending	K201685	-
Intended Use/ Indications	The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	SE
Prescription / OTC	Prescription use, only	Prescription use, only	SE
Principal of Operation	Monopolar or bipolar RF energy is delivered through micro needle electrode applying heat to target tissue to achieve coagulation and hemostasis	Monopolar or bipolar RF energy is delivered through micro needle electrode applying heat to target tissue to achieve coagulation and hemostasis	SE
Electrosurgical Unit	-	-	-
Operating Mode	Monopolar and Bipolar	Monopolar and Bipolar	SE
Output Frequency	1 MHz / 2 MHz	1 MHz / 2 MHz	SE
Nominal Operating Power	0 ~ 50 watt (step: 1 watt)	0 ~ 50 watt (step: 1 watt)	SE
Maximum Power Delivered to Patient	up to 50 W (step: 1 watt) (200 Ω)	up to 50 W (step: 1 watt) (200 Ω)	SE
Impedance	200 Ω	200 Ω	SE
Power Source	100 V - 240 V~, 50/60 Hz, 500 VA	100 V - 240 V~, 50/60 Hz, 500 VA	SE
Dimensions (mm)	503.2 (W) x 365.6 (L) x 316 (H)	503.2 (W) x 365.6 (L) x 316 (H)	SE
Weight	12.5 kg	12.5 kg	SE
Active Accessory (Electrode)	-	-	-
Operating Mode	Monopolar / Bipolar	Monopolar / Bipolar	SE

	Subject	***Predicate***	Substantial Equivalence
Electrode Tips	• Ten different electrode tips for the motor handpiece: S-49 TIP, I-49 TIP S-25 TIP, I-25 TIP, S-16 TIP, and I-16 TIP, C21-2 TIP, C21-1 TIP, CP-21 TIP, and C9 TIP • Three electrode needle tips for the AC handpiece: P1-08, A1-12, and A1-15 • ***Three electrode tips for the motor handpiece***: CP-16 TIP, CP-25 TIP and CP-49 TIP.	• Ten different electrode tips for the motor handpiece: TIP S-49, TIP I-49, TIP S-25, TIP I-25, TIP S-16, TIP I-16, C21-2 TIP, C21-1 TIP, CP-21 TIP, and C9 TIP Three electrode needle tips for the AC handpiece: P1-08, A1-12, and A1-15	Difference #1 • Different in the addition of **three** electrode tips for the motor handpiece
Electrode Type	Micro needle type	Micro needle type	SE
Electrode Tip Shelf-life	3 Years	2 Years	Difference #2
RF Treatment Area	Spot Size (Treated area): 1 cm x 1cm	Spot Size (Treated area): 1 cm x 1cm	SE
Enhanced engagement with tissue	Piston Mechanism	Piston Mechanism	SE
Material	Housing: Polycarbonate Insulation: Paracyclophane Needles: STS304	Housing: Polycarbonate Insulation: Paracyclophane Needles: STS304	SE
Single Use / Reusable	Single use	Single use	SE
Method of Sterilization	Ethylene Oxide gas (EO)	Ethylene Oxide gas (EO)	SE
Depth of Skin Ablation / Thickness	Depth of skin ablation: 0.5 ~ 2.5 mm (step: 0.25 mm) Thickness: 0.2 mm	Depth of skin ablation: 0.5 ~ 4.0 mm (step: 0.25 mm) Thickness: 0.2 mm	Difference #3
Neutral Electrode Pad	Neutral Electrode Pad for monopolar operation, K201685	Neutral Electrode Pad for monopolar operation, K201685	SE
Footswitch	-	-	SE
Function	Transmit RF energy to electrode	Transmit RF energy to electrode	SE
Performance	Single pole, single throw	Single pole, single throw	SE
Materials	Steel and plastic	Steel and plastic	SE

	Subject		***Predicate***		Substantial Equivalence
Other Characteristics	Single pedal, IPX8		Single pedal, IPX8		SE
Energy parameter	-		-		
Treatment Area (Dimension of the active part of the needles)	CP-49	7.8 mm X 7.8 mm	I-49	7.8 mm X 7.8mm	Difference #4
	CP-25	8.0 mm X 8.0 mm	I-25	8.0 mm X 8.0 mm	
	CP-16	3.9mm X 3.9 mm	I-16	7.8 mm X 7.8 mm	
Inter-needle spacing	CP-49	1.3 mm	I-49	1.3 mm	Difference #5
	CP-25	2.0 mm	I-25	2.0 mm	
	CP-16	1.3 mm	I-16	2.6 mm	
Max insertion depth	2.5 mm		4.0 mm		Difference #6
Min insertion depth	0.5mm		0.5mm		SE
Thickness of the needle	0.35mm		0.25mm		Difference #7
Max Power	50W		50W		SE

The intended use, dermatologic and general surgical procedures for electrocoagulation and hemostasis, of the ***subject device of*** POTENZA is identical to the intended use of the predicate device of POTENZA, cleared under K201685. The technological characteristics of the ***subject device of*** POTENZA are identical to the technological characteristics of the predicate device of POTENZA(K201685) with the sole exception of the addition of three invasive electrode tips (CP-16, CP-25, and CP-49) for changes to the labelling new electrode tips. For this difference in technological characteristics, reasonable safety and effectiveness can be assured by the completed Design Control and Risk Management activities. The technical characteristics of the CP-series tips are similar to the I-series tips. Performance testing of the added tips, CP-16, CP-25, CP-49, demonstrated substantial equivalence to the subject device, specifically the I-16, I-25, and I-49 tips.

6. Performance Characteristics

Verification and validation activities confirmed that the addition of four new electrode tips for the motor handpiece do not raise new or different questions of safety or effectiveness.

Testing confirmed the continued conformance to applicable technical design specifications and performance requirements including conformance to requirements of recognized consensus standards.

Biocompatibility Testing

Jeisys performed biocompatibility testing for the four newly added electrode tips according to FDA's "Use of International Standard ISO-10993, 'Biological

Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process'", June 6, 2016. The electrode tips are external communicating devices which come into contact with tissue / bone / dentin, for a limited period of time, i.e., less than 24 hours.

The electrode tips were tested as shown in Table 1 below.

Test Type	Standard	Results
Cytotoxicity	ISO 10993-05:2009, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity	*Pass*
Sensitization: Guinea Pig Maximization Test	ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	*Pass*
Irritation or Intracutaneous Reactivity	ISO 10993-23: Biological Evaluation of Medical Devices: Test for irritation, 2021	*Pass*
Acute Systemic Toxicity	ISO 10993- 11: Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity, 2017	*Pass*
Material Mediated Pyrogen Test	ISO 10993- 11: Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity, 2017	*Pass*
In-vitro Hemolysis Test direct contact method	ISO 10993-04: Biological Evaluation of Medical Devices - Part 04, Selection of Tests for Interactions with Blood, 2017/ ASTM F 756-17 (Standard Practice for the Assessment of Hemolytic Properties of Materials)	*Pass*
In-vitro Hemolysis Test Indirect Method	ISO 10993-04: Biological Evaluation of Medical Devices - Part 04, Selection of Tests for Interactions with Blood, 2017/ ASTM F 756-17 (Standard Practice for the Assessment of Hemolytic Properties of Materials)	*Pass*

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety, EMC, device-related electrical safety for high frequency and usability were conducted on the ***subject device*** system according to the following consensus standards:

- 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
- 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

Bench Testing

Jeisys conducted bench testing to assure that the POTENZA operates safely and within the predefined design specifications. Tested parameters included:

- Output accuracy (Monopolar at 1MHz and 2 MHz)
- Output accuracy (Bipolar at 1MHz and 2MHz)
- Frequency: manual and standard
- Power fluctuation characteristics
- Negative output protection
- Impedance measurement accuracy and range
- HO count accuracy
- Safety test of various warnings / failsafe mechanisms
- Needle depth
- Motor speed level
- *Ex Vivo* testing conducted on three types of tissue – Liver, Kidney and Muscle under GLP Thermal testing in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", August 15, 2014

Clinical Studies

No clinical performance testing was performed.

CONCLUSIONS

The subject device (POTENZA) is the same as the predicate device (K201685) with respect to the principles of operation, technological characteristics, as well as performance characteristics. Non-clinical testing was conducted to evaluate the performance of the subject device in comparison to the predicate device. Results of design validation and verification activities, i.e., testing to designated standards and performance testing of the devices, have demonstrated substantial equivalence of the subject device to the predicate in terms of safety and effectiveness for requested intended use.