January 19, 2021

Jeisys Medical, Inc.
% Ms. Pamela Weagraff, MBA
Senior Principal
MedTech Regulatory Solutions – North America
IQVIA MedTech
18 Bridie Lane
Norfolk, Massachusetts 02056

Re: K201685
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
Dated: October 30,2020
Received: November 2, 2020

Dear Ms. Weagraff:

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201685

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.

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510(k) Summary[1]

I. TRADITIONAL 510(K) SUBMITTER

a) Company Name and Address

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d) Date Prepared: January 11, 2021

II. 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

III. PREDICATE DEVICE

POTENZA, cleared under Traditional 510(k) K192545.

[1] Prepared according to FDA's "Guidance for Industry and FDA Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" July 24, 2014

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

IV. DEVICE DESCRIPTION

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

The POTENZA consists of the following components:

- Electrosurgical Unit - Main body
- Two different handpieces (motor and AC)
- Six different electrode tips for the motor handpiece and three needle tips for the AC handpiece; provided as single use, sterile products
- Neutral electrode pad and neutral electrode pad cable, cleared under K092761
- Handpiece stand
- Foot switch
- Power cord

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.

V. INDICATIONS FOR USE

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE

a) PREDICATE DEVICE

The predicate device, POTENZA, cleared under K192545, is an RF (radiofrequency), software-controlled electrosurgical devices used for electrocoagulation of soft tissue and hemostasis. The device consists of the following components:

- Electrosurgical Unit - Main body
- Two different handpieces (motor and AC)
- Neutral electrode pad and neutral electrode pad cable, cleared under K092761
- Handpiece stand
- Foot switch
- Power cord

In this Traditional 510(k), four additional electrode tips are being added to the six different electrode tips for the motor handpiece. All electrode tips are provided as single use, sterile products. The four newly added electrode tips for the motor handpiece are: C21-2 TIP, C21-1 TIP, CP-21 TIP, and C9 TIP, for monopolar and bipolar operating modes. Changes have been made to the instructions for use and to the packaging labels to include the four new tips.

The fundamental technological features of the POTENZA and its intended use are the same as the predicate device.

- Principle of operation of the POTENZA with the four additional electrode tips: ***same*** as the predicate devices with respect delivery of bipolar RF energy through micro needle electrode to achieve coagulation and hemostasis. It differs from the predicate device, in that the four newly added electrode tips were not available for the predicate device.
- Electrosurgical Unit:
  - Bipolar and monopolar operating mode: ***same*** as for the predicate device.
  - Output frequency of 1MHz and 2 MHz: ***same*** as for the predicate device.
  - Operating levels up to 50 W, at 10 different levels: ***same*** as for the predicate device.
  - Maximum power available: ***same*** as predicate device.
  - Impedance available: ***same*** as predicate device.
  - Power source: ***same*** as predicate device.
- Active Accessory (Electrode):
  - Bipolar and monopolar operating mode: ***same*** as the predicate device.
  - Electrode types: four new electrode tips are being added to the six different electrode tips for the motor handpiece. All electrode tips are provided as single use, sterile products. The four newly added electrode tips for the motor handpiece are: C21-2 TIP, C21-1 TIP, CP-21 TIP, and C9 TIP, for bi-polar and monopolar operation.
  - RF treatment area: ***same*** as the predicate device.
  - Material of four new electrode tips: similar to predicate device; performance testing and biocompatibility testing has been completed.
  - Four new electrode tips - are intended for single use: ***same*** as the predicate device.
  - Depth of skin ablation, 0.5~2.5 mm: ***same*** as predicate device; within range of ablation depth of predicate device..

VII. PERFORMANCE DATA

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.

a) 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.

Table 1: Biocompatibility Testing Requirements and Results

Test Type / Method	Acceptance Criteria	Results
Extractables: ISO 10993-12:2012, Biological evaluation of medical devices – Part 12, Sample preparation and reference materials	Property – per standard	Pass
	pH ≤ 1.5	Pass
	Potassium permanganate reducing substances ≤ 2.0 mL	Pass
	Residue after evaporation ≤ 1.0 mg	Pass
	UV spectrum (250 nm – 350 nm) ≤ 0.1	Pass
	Heavy Metals per standard	Pass
Cytoxicity: • ISO 10993-05:2009, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity • USP 41:2018 <87> Biological Reactivity Tests, *in vitro* elution test	Meet requirements of standard	Pass
Sensitization: Guinea Pig Maximization Test (GPMT): ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Meet requirements of standard	Pass

Test Type / Method	Acceptance Criteria	Results
Irritation or Intracutaneous Reactivity [Animal Intracutaneous (Intradermal) Reactivity Test: ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Meet requirements of standard	Pass
Acute Systemic Toxicity: ISO10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Meet requirements of standard	Pass
Hemolysis: • ISO 10993-4, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood • ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials	Meet requirements of standard	Pass
USP Rabbit Pyrogen: • ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity • USP, General Chapter < 151 >, Pyrogen Test	Meet requirements of standard / USP	Pass

b) Electrical Safety and Electromagnetic Compatibility (EMC)

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

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2-12, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance
- IEC 60101-2-2:2017, 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
- IEC 60601-1-6:2010, AMDI:2013, Medical electrical equipment Part 1-6, General requirements for Safety – Collateral Standard: Usability

c) Software Verification and Validation Testing

Software verification and validation testing was conducted for the subject device, and documentation was provided in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005, commensurate with a moderate level of concern.

d) Bench Testing

Jeisys conducted bench testing to assure that the four new electrode pins operate safely and within the predefined design specifications when used with the POTENZA.

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
- HP count accuracy
- Safety test of various warnings / failsafe mechanisms
- Needle depth
- Motor speed level
- 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

e) Sterilization

The four new electrode tips are subject to Ethylene Oxide (EO) sterilization. EO sterilization residual testing for the four new electrode tips according to ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals to acceptance criteria as specified in the standard.

According to 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, the sterility assurance level (SAL) is 10^{-6}.

f) Shelf-life (Accelerated Aging) / Sterility

Jeisys performed shelf-life testing to establish a two year shelf-life based on 65-days accelerated aging in accordance with the following standards to the acceptance criteria as specified in the standard:

- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices – Accelerated Aging
- USP <71>, Sterility Tests 42-NF37 – Sterility

- ASTM F1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration – Packaging Test

g) Animal Studies / Clinical Studies

The addition of the four new electrode pins did not require animal testing or clinical testing in humans.

VIII. CONCLUSIONS

The POTENZA device with the addition of the four new electrodes is similar to the predicate device 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 four newly added electrode pins 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.