October 31, 2019

Apyx Medical Corporation (formerly Bovie Medical)
% Dave Yungvirt
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K192867
Trade/Device Name: Apyx Helium Plasma Generator (APYX-200H/P, APYX-JS3/RS3)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 3, 2019
Received: October 7, 2019

Dear Dave Yungvirt:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192867

Device Name
Apyx Helium Plasma Generators (APYX-200H, APYX-200P, APYX-JS3, APYX-RS3)

Indications for Use *(Describe)*
The Apyx Helium Plasma Generators (owned by Apyx Medical) are indicated for delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/ J-Plasma handpieces.

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

1. General Information

Submitted by:

Apyx Medical Corporation (formerly Bovie Medical)
5115 Ulmerton Road
Clearwater, Florida 33760-4004
United States of America

Establishment Registration #: 3007593903

Submitter FAX Number: (727) 322-4465

Contact Person:

Dr. Libet Garber, Global Director of Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760-4004
United States of America
Phone: (727) 803-8512
Email: Libet.Garber@apyxmedical.com

Date Prepared: September 23, 2019

Trade Names (Model Number): **Apyx Helium Plasma Generator**
(APYX-200H/P, APYX-JS3/RS3)

Common Name: Electrosurgical Generator

Classification: Class II per 21CFR 878.4400 - Electrosurgical Cutting and Coagulation Device and Accessories
Product Code: GEI

Predicate Device(s):

Predicate Device
Bovie Ultimate Gen 2 High Frequency Electrosurgical Generator (K170188)

2. Indications for Use

The Apyx Helium Plasma Generators (owned by Apyx Medical) are indicated for delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/ J-Plasma handpieces.

3. Device Description

The Apyx Helium Plasma Generator is an electrosurgical device that delivers radiofrequency (RF) energy to cut and coagulate soft tissue. It can also deliver Helium plasma energy for cutting, coagulation, and ablation of soft tissue. Like the predicate, the Apyx Helium Plasma Generator provides standard electrosurgical energy and Helium Plasma energy, and there are no changes to the intended use, performance specifications, electrosurgical modes, output power waveforms or maximum power settings. Essentially, the Apyx Helium Plasma Generator is a combination of a standard electrosurgical generator and a Helium Plasma generator.

4. Technological Characteristics and Performance Specifications

The Apyx Helium Plasma Generators is a modified version of the primary predicate device that was cleared under K170188 (Bovie Ultimate® Gen 2 Electrosurgical Generator). There are no changes to intended use or principles of operation.

The Apyx Helium Plasma Generator was modified to enhance the user interface and to comply with the new revision of the IEC 60601-2-2:2017 standard. Additionally, the gas pressure regulation was upgraded for better gas control.

5. Performance Data

Electrical safety and electromagnetic compatibility (EMC) testing were conducted, and the results demonstrated that the Apyx Helium Plasma Generator performance is in accordance with the following standards:

International Standard	Description
ANSI/AAMI/IEC ES60601-1:2005/(R)2012 and A1:2012	*Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*
AAMI/ANSI/IEC 60601-1-2:2014 (4th Edition)	*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
AAMI/ANSI/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 and Software verification and validation testing were completed according to a moderate level of concern to demonstrate substantial equivalence of the subject device to the predicate device (K170188):

Test	Objective	Results
Electrical Verification	To verify electrical product and performance specification requirements.	The electrical functionality of the generator was verified to meet performance specification requirements.
Software Verification & Validation for Main, Display and Gas Boards	To validate the field programmable gate array (FPGA) procedure and the logic design used in the generator.	The results demonstrated that the system and FPGA perform as intended and according to the product specifications.
Mechanical Verification	To verify mechanical product and performance specification requirements.	The results verified that the mechanical design meets the product and performance requirements.

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510(k) Summary

Results of the bench and software testing demonstrate that the Apyx Helium Plasma Generators are equivalent to the predicate device in terms of safety and effectiveness.

6. Substantial Equivalence

Feature/ Characteristic	Predicate Device	Subject Device	SE Rationale
	Bovie Ultimate Gen 2 Electrosurgical Generator (K170188)	**Apyx Helium Plasma Generator**	
Indications for Use	The Bovie Ultimate® Electrosurgical Generators are indicated for delivery of radiofrequency energy and/or helium gas plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The J-plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces.	The Apyx Helium Plasma Generators (owned by Apyx Medical) are indicated for delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/ J-Plasma handpieces.	The intended use is the same, with some language differences due to the company name change and branding (i.e., Bovie Medical to Apyx Medical).
Technology / Energy Used, Delivered	Uses High Frequency Radiofrequency (RF) energy to create clinical effect. The electrical properties of the waveform (frequency, peak, and duration) produce the clinical effect (i.e. coagulation and cutting). For soft tissue coagulation using Helium gas, the flow rate produces clinical effect (i.e. coagulation and ablation).	Uses High Frequency Radiofrequency (RF) energy to create clinical effect. The electrical properties of the waveform (frequency, peak, and duration) produce the clinical effect (i.e. coagulation and cutting). For soft tissue coagulation using Helium gas, the flow rate produces clinical effect (i.e. coagulation and ablation).	Same
User Interface	Push buttons, Seven segment display and LEDs.	Push buttons, Seven segment display and LEDs.	Same
Available Modes	Cut (2), Blend (3), Coagulation (3: pinpoint, spray, gentle), Bipolar (3: Macro, Micro, Standard), and J-Plasma (2 -with Active accessory and with Passive accessory)	Cut (2), Blend (3), Coagulation (3: pinpoint, spray, gentle), Bipolar (3: Macro, Micro, Standard) with auto bipolar option, and J-Plasma (2 -with Active accessory and with Passive accessory)	Same modes with the option of an auto-bipolar feature that was cleared in K134054

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510(k) Summary

Feature/ Characteristic	Predicate Device	Subject Device	SE Rationale
	Bovie Ultimate Gen 2 Electrosurgical Generator (K170188)	**Apyx Helium Plasma Generator**	
Electrical Safety Standards	Complies with ES60601-1 (third edition), IEC60601-1-2(electromagnetic compatibility), and IEC60601-2-2 standard for the safety of electrosurgical equipment.	Complies with ES60601-1 (third edition), IEC60601-1-2 (electromagnetic compatibility), and IEC60601-2-2 (2017) standard for the safety of electrosurgical equipment.	Equivalent

7. Conclusion

The Apyx Helium Plasma Generator is a modification to the predicate device that was cleared in K170188 (Bovie Ultimate® Gen 2 Electrosurgical Generator). There are no changes to the intended use, principle of operation or mechanism of action. The subject device, like the predicate device, is intended for delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures.

Technological differences between the Apyx Plasma Generator and the predicate do not raise any new concerns of safety or effectiveness and the performance testing demonstrated that the device performs as intended because:

- Electrical safety and EMC testing demonstrated that the Apyx Helium Plasma Generator complies with the applicable FDA recognized IEC-60601 standards.
- Electrical Verification testing demonstrated that the product and performance specification requirements were met.
- Software verification and validation demonstrated that the generator performs as intended and according to the product specifications.
- Mechanical Verification confirmed that the mechanical design meets the product and performance requirements.

Therefore, the device has the same technological characteristics as the predicate and can be determined to be substantially equivalent in term of safety and effectiveness.