



July 30, 2019

Apyx Medical Corporation (formerly Bovie Medical)  
Dr. Topaz Kirlew  
Vice President QA & RA  
5115 Ulmerton Road  
Clearwater, Florida 33760

Re: K191484

Trade/Device Name: Renuvion/J-Plasma Precise Handpiece (Model # BVX-330 BPS)  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: June 4, 2019  
Received: June 4, 2019

Dear Dr. Kirlew:

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/pmnmn.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 and Part 809); 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](mailto: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

## Indications for Use

510(k) Number (if known)

K191484

Device Name

Renuvion®/J-Plasma® Precise Handpiece (BVX-330 BPS)

Indications for Use (Describe)

The Renuvion®/J-Plasma® Precise Handpiece is intended to be used with compatible electrosurgical generators for the delivery of helium plasma for cutting, coagulation and ablation of soft tissue during open and laparoscopic surgical procedures. The Renuvion®/J-Plasma® Precise Handpiece is compatible with the Electrosurgical Generators BVX-200H and BVX-200P manufactured by Apyx Medical.

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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**1. General Information:**

**Submitted by:** Apyx Medical Corporation (formerly Bovie Medical)  
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Clearwater, Florida 33760 -4004  
United States of America

**Establishment Registration #:** 3007593903

**Submitter FAX Number:** (727) 322-4465

**Contact Person:** Dr. Topaz Kirlew, Vice President, QA & RA  
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**Date Prepared:** July 30, 2019

**Trade Names (Model Number):** **Renuvion®/J-Plasma® Precise Handpiece**  
(BVX-330 BPS)

**Common Name:** Electrosurgical Handpiece

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

**Predicate Devices:** Primary Predicate Device  
Renuvion®/ J-Plasma® Precise Handpiece (K183610 &  
K151325)

Reference Device  
Renuvion®/ J-Plasma® Precise Open Handpiece  
(K183610 & K170188)

**2. Intended Use / Indications for Use:**

The **Renuvion®/J-Plasma® Precise Handpiece** is intended to be used with compatible electrosurgical generators for the delivery of helium plasma for cutting, coagulation and ablation of soft tissue during open and laparoscopic surgical procedures.

The Renuvion®/J-Plasma® Precise Handpiece is compatible with the Electrosurgical Generators BVX-200H and BVX-200P manufactured by Apyx Medical.

**3. Device Description Renuvion/J-Plasma Precise Handpiece:**

The Renuvion<sup>®</sup>/J-Plasma<sup>®</sup> Precise Handpiece is a sterile, single use electrosurgical accessory intended to be used in conjunction with compatible electrosurgical generators for the delivery of helium gas plasma for cutting, coagulating, and ablating soft tissue. The compatible Generators operate at an adjustable power of up to 40W (expressed as 0-100% where 100% is 40W) and provide an adjustable helium gas flow of 1-5 LPM. The Renuvion/J-Plasma Precise Handpiece is available with a retractable cutting tip blade for excising tissue. The blade tip serves as an electrode to generate helium plasma.

The blade can be extended in 2mm increments from 0 to 10mm from the distal tip of the shaft via a ratcheted slider and retracted via a release latch. The device is activated via pressing the purple activation trigger. The handpiece is to be used with compatible electrosurgical generators, BVX-200H or BVX-200P, manufactured by Apyx Medical.

The Renuvion<sup>®</sup>/J-Plasma<sup>®</sup> Precise Handpiece is available in a 33 cm length for use in laparoscopic or open surgical procedures. The 33 cm is a standard length for laparoscopic instruments and are compatible with standard 5 mm trocars.

**4. Technological Characteristics:**

The subject device, Renuvion<sup>®</sup>/J-Plasma<sup>®</sup> Precise Handpiece (without the transformer) is a modification to the legally marketed Primary Predicate Device (K183610 & K151325) with the same name. The modification consists of a design change to remove the transformer from the base of this pistol shaped handpiece (HP) and the addition of the Monopolar Coagulation mode. This removal of the transformer from the handpiece is being implemented to improve manufacturability and device ergonomics. There is no change to the handpiece geometry or shaft length, no change to materials and no technology or performance change other than changes in product specifications. There is no change to the Indications for Use or operational principles.

The Subject, Primary Predicate and Reference devices all use the same basic technology, deliver the same J-Plasma helium plasma energy and are compatible only with the Electrosurgical Generators (BVX-200H and BVX-200P) manufactured by Apyx Medical.

The removal of the transformer from the subject device handpiece improves ergonomics since it is 39% lighter than the Primary Predicate device (K183610 & K151325) and improves manufacturability (efficiency, cost and speed).

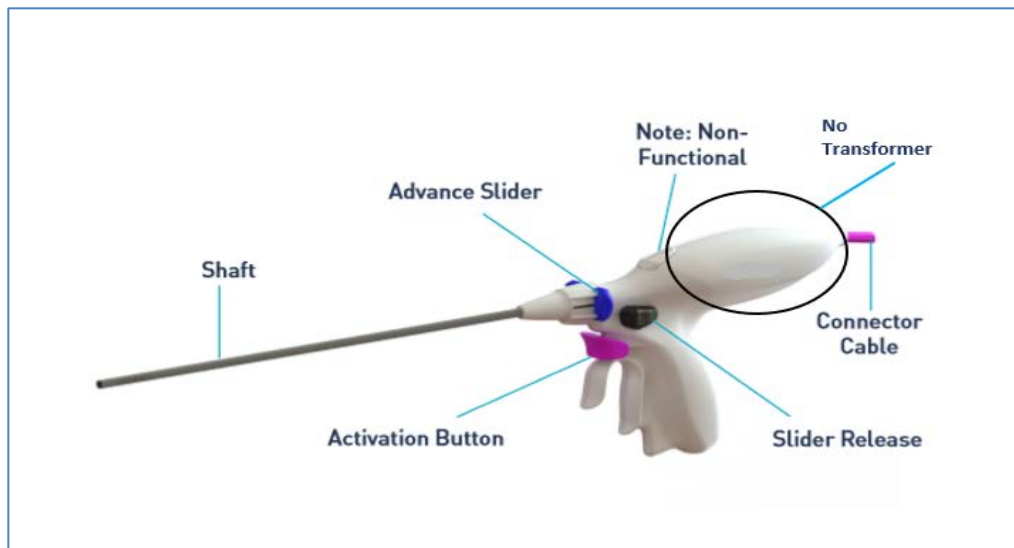
The removal of the transformer from the handpiece does not affect the functionality of the handpiece because the compatible electrosurgical generators (BVX-200H and BVX-200P) have transformers already built into them and are capable of supporting the subject device without any changes to these generators. The Reference Device (Renuvion/J-Plasma Precise Open Handpiece, K183610 & K170188) also functions by using the transformer in the

electrosurgical generator resulting in the following identical characteristics being shared with the subject device:

- The internal transformer located at the base of the handpiece has been removed.
- Availability of the Monopolar Coagulation feature (via optional foot pedal) for enhanced coagulation - gives the user the ability to use the Monopolar Coagulation mode on the compatible electrosurgical generator without having to switch to a secondary electrode handpiece.
- Can access 'Contact J-Plasma' by double clicking the button or foot pedal which tells the compatible electrosurgical generator that the intention is to cut (this feature on the compatible electrosurgical generators was cleared in K170188).

Bench testing has demonstrated that the tissue effect of the subject device and the Primary Predicate device (Renuvion/J-Plasma Precise Handpiece, K183610 & K151325) using the J-Plasma mode are equivalent and bench testing has also demonstrated that the tissue effect of the subject device and the Reference device (Renuvion/J-Plasma Precise Open Handpiece, K183610 & K170188) using the Monopolar Coagulation mode are equivalent. The results of design validation demonstrate that the tissue effect meets the user needs for cutting, coagulation and ablation of soft tissue.

The Apyx J-Plasma Precise Handpiece is pictured below with the circled area depicting the location at the base of the handpiece where the transformer has been removed.



**5. Performance Data:**

**a) Bench Testing**

All testing performed on the subject device, Renuvion®/J-Plasma® Precise Handpiece (without transformer), was derived from the risk assessment in accordance with ISO 14971 which evaluated the safety and effectiveness of the design modification in

accordance with Apyx Medical’s design and development procedures. The test methodology and acceptance criteria were developed from the same standards and internal Design and Development procedures used for clearance of the Primary Predicate and Reference devices.

Performance testing to assure that the subject device met performance requirements was conducted in accordance with protocols to verify design specifications. The testing performed is summarized in the following table:

Test	Objective	Result
Mechanical Performance & Functionality	Verify Mechanical functionality of the Renuvion®/J-Plasma® Precise Handpiece	Mechanical functionality requirements met
Tissue Effect (Plasma Activation)	Verify that the tissue effects are the similar between the subject device and the Primary Predicate device (K183610 & K151325)	Tissue effects are equivalent between the subject device and Primary Predicate device
Tissue Effect (Monopolar Coagulation)	Verify that the tissue effects are the similar between the subject device and the Reference device (K183610 & K170188)	Tissue effects are equivalent between the subject device and Reference device

**b) Electrical Safety and Electromagnetic Compatibility (EMC)**

Electrical safety and EMC testing were conducted on the subject device, Renuvion/J-Plasma Precise Handpiece (without transformer). The handpiece complies with the IEC 60601-1, and IEC 60601-2-2 standards for safety and the IEC 60601-1-2 standard for EMC. The subject device, Renuvion/J-Plasma Precise Handpiece (without transformer), was determined to be in conformance with these standards.

**c) Biocompatibility Testing**

The biocompatibility evaluation for the subject device, Renuvion/J-Plasma Precise Handpiece (without transformer), was conducted in accordance with the FDA guidance; “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.” The Biocompatibility testing for the patient and user contacting materials for the subject device, Renuvion/J-Plasma Precise Handpiece (without transformer), was either conducted or was previously submitted to the FDA in 510(k)s cleared under the Primary Predicate and Reference devices (K183610, K151325 & K170188). The battery of evaluations included the following testing:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Hemolysis

- Material Mediated Pyrogen/Pyrogenicity

The Renuvion/J-Plasma Precise Handpiece (subject device) is an external communicating device with an indirect blood path contact for a duration of less than 24 hours. Biocompatibility has been established per ISO 10993 guidelines for this category. Biocompatibility verification testing was satisfactorily conducted for the subject device.

**6. Substantial Equivalence:**

<b>Feature/ Characteristic</b>	<b>Subject Device Renuvion®/J-Plasma Precise HP (without transformer)</b>	<b>1° Predicate Device Renuvion®/J-Plasma Precise HP (K138610 &amp; K151325)</b>	<b>Reference Device Renuvion®/J-Plasma Precise Open HP (K138610 &amp; K170188)</b>
<b>Intended Use</b>	Same	Same	Similar
<b>Energy Source</b>	RF Generator; Only with Bovie/Apyx J-Plasma Generators	Same	Same
<b>Location of Transformer</b>	Electrosurgical Generator	Handpiece	Electrosurgical Generator
<b>Handpiece weight</b>	221.3 g	362.8 g	N/A
<b>Energy Type</b>	Helium gas plasma; Monopolar coagulation	Helium gas plasma	Helium gas plasma; Monopolar coagulation
<b>Output</b>	Monopolar	Same	Same
<b>Plasma settings</b>	Maximum 40 watts, 1-5 LPM gas flow	Same	Same
<b>Monopolar Coagulation Mode &amp; Settings</b>	Yes; Maximum 120 watts, 1-5 lpm gas flow	No - feature not available	Yes; Maximum 120 watts, 1-5 lpm gas flow
<b>Monopolar Coagulation Tissue Effect</b>	Same	N/A – feature not available	Same
<b>Plasma Activation Tissue Effect</b>	Same	Same	N/A
<b>Device Activation</b>	Hand Activation with 1 button (J-Plasma) or optional Foot Activation with 2-foot pedals (J-Plasma, monopolar coagulation)	Hand Activation with 1 button (J-Plasma)	Hand Activation with 2 buttons (J-Plasma, monopolar coagulation) or optional Foot Activation with 2-foot pedals (J-Plasma, monopolar coagulation)
<b>System Components</b>	Same	Same	Same
<b>User Interface</b>	Straight	Same	Same
<b>Connector</b>	Company Proprietary - per design change reflected in K183610 that establishes both	Same	Same



Feature/ Characteristic	Subject Device <b>Renuvion®/J-Plasma Precise HP</b> (without transformer)	1° Predicate Device <b>Renuvion®/J-Plasma Precise HP</b> (K138610 & K151325)	Reference Device <b>Renuvion®/J-Plasma Precise Open HP</b> (K138610 & K170188)
	pneumatic seal and electrical connection		

**7. Conclusion:**

The subject device, **Renuvion® / J-Plasma® Precise Handpiece** (without the transformer), has the same intended use, indications for use, operational principles, device ergonomics, handle geometry, handpiece geometry, and shaft length as the originally designed Primary Predicate device (Renuvion/J-Plasma Precise Handpiece, K183610 & K151325) of the same name.

The technological difference between the subject and Primary Predicate devices is the physical location of the transformer (moved from the handpiece to the electrosurgical generator) to reduce weight for easier handling as well as improve manufacturability, and availability of the Monopolar Coagulation feature (via optional foot pedal) to give the user the ability to use the Monopolar Coagulation mode on the compatible electrosurgical generator without having to switch to a secondary electrode handpiece. Bench testing has demonstrated that the tissue effects of the subject device are equivalent to the tissue effects of the Primary Predicate device (Renuvion/J-Plasma Precise Handpiece, K183610 & K151325) in the J-Plasma mode and the tissue effects of the subject device are also equivalent to the Reference device (Renuvion/J-Plasma Precise Open Handpiece, K183610 & K170188) in the Monopolar Coagulation mode.

The subject device's safety and performance have been confirmed by results of the performance bench testing and the design change has gone through the design controls process and the proper verification and validation demonstrate that the device performs as intended. Therefore, there are no differences that would raise new or different questions regarding safety or effectiveness as the subject device, Primary Predicate device and the Reference device all operate in a similar manner with an equivalent range of tissue treatment parameters.