



October 11, 2019

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

Re: K191542

Trade/Device Name: Apyx Plasma/RF Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 10, 2019
Received: June 11, 2019

Dear Topaz 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/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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K191542

Device Name

Apyx Plasma/RF Handpiece (APYX-15-SP, APYX-15-TP and APXY-27-TP)

Indications for Use (Describe)

The Apyx Plasma/RF Handpiece is intended to be used with compatible electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures. The Apyx Plasma/RF Handpiece is compatible with the Electrosurgical Generators, BVX-200H and BVX-200P, owned 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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510(k) Summary

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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. Topaz Kirlew, Vice President, QA & RA
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United States of America
Phone: (727) 803-8617
Email: topaz.kirlew@apyxmedical.com

Date Prepared: June 10, 2019

Trade Names (Model Numbers): **Apyx Plasma/RF Handpiece**
(APYX-15-SP, APYX-15-TP, APYX-27-TP)

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

Reference Devices
Thermi Temperature Controlled Radiofrequency (RF)
System (K173582) & Thermi Injectable RF Electrodes
(K170116)

2. Indications for Use:

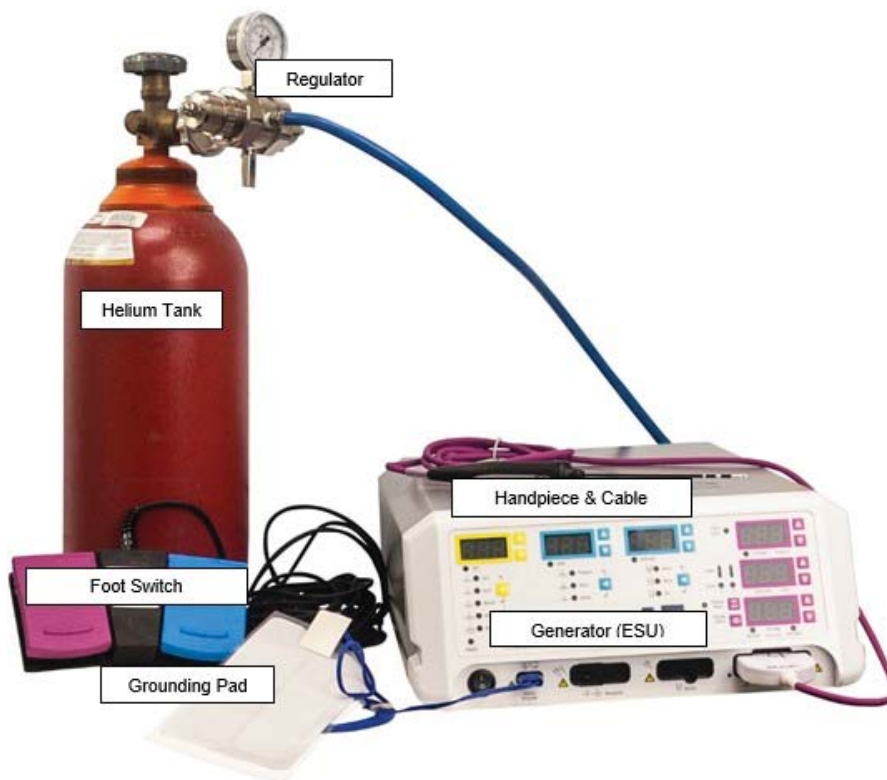
The **Apyx Plasma/RF Handpiece** (HP) is intended to be used with compatible electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures. The Apyx Plasma/RF

Handpiece is compatible with the Electrosurgical Generators BVX-200H and BVX-200P owned by Apyx Medical.

3. Device Description:

The **Apyx Plasma/RF Handpiece** is a sterile, single use electrosurgical (monopolar) device intended to be used in conjunction with compatible generators for the percutaneous delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of 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. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue cutting, coagulation or ablation.

The Apyx Plasma/RF Handpiece has a non-extendable electrode to generate helium plasma. The handpiece is available in two different lengths: 15cm and 27cm. The 15cm length is available in a single port (APYX-15-SP) as well as a twin port configuration (APYX-15-TP). The 27cm length is only available with a twin port configuration (APYX-27-TP). The Apyx Plasma/RF System with all components and accessories is depicted in the picture below.



4. Technological Characteristics:

The Apyx Plasma/RF Handpiece is a modification to the primary predicate device that was cleared in K183610 & K170188 (Renuvion®/J-Plasma® Precise Open Handpiece). There are no changes to indications for use, principle of operation, mechanism of action or sterilization methods.

The Apyx Plasma/RF Handpiece as compared to the primary predicate device (K183610 & K170188) has only the following differences in technological characteristics:

- ✓ All models will have a side port configuration to allow the plasma to exit the handpiece through the side vs. from the point tip.
- ✓ All 3 configurations will have a 'bullet shape' point tip and the electrode is not extendable.
- ✓ The handle is thicker, and the shaft diameter is smaller (3.0 mm shaft vs. 5.0 mm shaft) and more flexible with tip distance indicators at the end.
- ✓ Shaft length of one model is 27cm long (the primary predicate device used for clearance of the Renuvion/J-Plasma® Precise Open Handpiece is the Renuvion/J-Plasma® Handpiece (K151325) that has a shaft length of 27cm and was also cleared in K183610).

The **Apyx Plasma/RF Handpiece** with its components is pictured below.



Results of bench and animal testing demonstrate that the Apyx Plasma/RF Handpiece is at least as safe and effective as the primary predicate devices.

5. Performance Data:

a. Bench Testing

All testing performed on the Apyx Plasma/RF System was derived from the risk assessment in accordance with ISO 14971 which evaluated the safety and effectiveness



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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 devices owned by Apyx Medical. Performance testing to assure that the subject Apyx Plasma/RF System met performance requirements was conducted in accordance with protocols to verify design specifications. The testing performed are summarized in the following table:

| Test | Objective | Result |
|--|--|---|
| Mechanical Verification & Functionality | Verify Mechanical functionality of the Apyx Plasma/RF Handpiece | Mechanical functionality requirements met |
| Energy & Power Output | <p>Verify via Calorimetric testing that the tissue effects are equivalent between the devices sharing the Renuvion/J-Plasma technology that are owned by Apyx Medical –</p> <ul style="list-style-type: none"> ▪ Subject device (Apyx Plasma/RF Handpiece); ▪ Primary Predicate device cleared under K183610 & K170188 (Renuvion/J-Plasma® Precise Open Handpiece); and ▪ Predicate device cleared under K183610 & K151325 (Renuvion/J-Plasma® Precise Handpiece) | There are no significant differences in energy and power outputs between the subject device, Primary Predicate devices owned by Apyx Medical; all 3 devices will deliver the same amount of energy to tissue at equivalent generator settings |

b. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Apyx Plasma/RF System. The handpiece complies with the ANSI/AAMI/IEC 60601-1:2015/(R)2012 and A1:2012, and AAMI/ANSI/IEC 60601-2-2:2017 standards for safety and the AAMI/ANSI/IEC 60601-1-2:2014 (4th Edition) standard for EMC. The Apyx Plasma/RF System was determined to be in conformance with these standards.

c. Biocompatibility Testing

The biocompatibility evaluation for the Apyx Plasma/RF Handpiece was conducted in accordance with the June 16, 2016 FDA Guidance, "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and the AAMI/ANSI/ISO 10993-1:2009/(R2013) standard,

“Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process”. The battery of testing was either conducted or was previously submitted to the FDA in 510(k)s cleared under the predicate devices (K183610, K151325 & K170188). The battery of evaluations included the following testing:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Hemolysis
- Material Mediated Pyrogen/Pyrogenicity

The Apyx Plasma/RF 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. Pre-Clinical & Ex-Vivo Studies:

- a. **Tissue Temperature Profile Equivalency** – Pre-clinical testing was conducted to establish and compare the tissue temperature profiles of the devices owned by Apyx Medical and that share the Renuvion/J-Plasma technology: the subject device (Apyx Plasma/RF Handpiece), the predicate devices (Renuvion/J-Plasma® Precise Open Handpiece and Renuvion/J-Plasma® Precise Handpiece). Testing involved device activation on porcine skin while capturing the skin temperatures using a thermal video camera. Testing demonstrated that the three devices heat tissue in an equivalent manner.
 - b. **Maximum Temperature Study for Renuvion/J-Plasma Technology Family** – A pre-clinical study was conducted in a live porcine model to quantify the internal and external tissue temperatures (via a thermal video camera) resulting from the use of the Renuvion/J-Plasma® technology for soft tissue coagulation and to determine the effect of multiple variables on the tissue temperatures. These temperatures were recorded after performing six consecutive passes of the Renuvion/J-Plasma® technology under the same area of tissue to represent a “worst case” scenario. However, even in this “worst case” scenario, the epidermal surface temperature remained below 41°C and within safe limits (below 47°C)*. The results of this testing demonstrate that safe skin temperatures are maintained with the Renuvion/J-Plasma® Technology and skin temperature monitoring is not indicated due to this unique mechanism of action. This is different from devices such as the Reference Device (Thermi Temperature Controlled Radiofrequency (RF) System, K173582 & Thermi Injectable RF Electrodes, K170116) that work on the principle of bulk tissue heating in order to achieve coagulation of soft tissue and where monopolar energy is primarily directed into the dermis thus necessitating skin temperature monitoring.
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- c. **Tissue Thermal Effect Equivalency Test for Apyx Plasma RF Device** – An ex-vivo study was conducted on several tissue types (i.e., muscle, liver, kidney) to compare the tissue thermal effect of the Apyx Plasma/RF Handpiece and the predicate device. The quantitative results of this testing demonstrated that the tissue effects of all the subject device models (APYX-27-TP, APYX-15-TP and APYX-15-SP) are equivalent to the predicate device's effect over a range of power and flow settings that are clinically relevant.

The pre-clinical and ex-vivo testing discussed above is summarized in the table below:

| Test | Objective | Result |
|--|--|--|
| Tissue Temperature Profile Equivalency | Compare the tissue temperature profiles of the devices owned by Apyx Medical and that share the Renuvion/J-Plasma® technology (subject device & primary predicate devices,) via device activation on porcine skin while capturing the skin temperatures using a thermal video camera. | The subject device (Apyx Plasma/RF Handpiece) and predicate devices (Renuvion/J-Plasma® Precise Open Handpiece & Renuvion/J-Plasma® Precise Handpiece) all heat tissue in an equivalent manner and are substantially equivalent in terms of tissue effect for the coagulation of soft tissue. |
| Maximum Internal & External Temperature Study | Quantify the internal and external tissue temperatures (via a thermal video camera) resulting from the use of the Renuvion/J-Plasma® technology for soft tissue coagulation in a worst-case scenario and to determine the effect of multiple variables on the tissue temperatures in a live porcine model. | The porcine skin epidermal surface temperature remained below 41°C and within safe limits (below 47°C) * even with 6 passes in the same area. The results of this testing demonstrate that safe skin temperatures are maintained with the Renuvion/J-Plasma® Technology and skin temperature monitoring is not indicated due to this unique mechanism of action. |
| Thermal Tissue Effect Comparison | Verify that the Apyx Plasma/RF Handpiece produces equivalent ex-vivo tissue effect when compared to the Predicate Device. | The depth and lateral spread (i.e., average of length and width) of thermal effect measured for the Apyx Plasma/RF handpiece were equivalent to the predicate device's thermal effect as measured over a range of power and flow settings which include worst-case clinical scenarios. |

* Chen SS, Wright NT, Humphrey JD. Heat-induced changes in the mechanics of a collagenous tissue: isothermal free shrinkage. *Journal of Biomechanical Engineering* 1997;109:372-378.



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7. Substantial Equivalence:

| Feature/ Characteristic | Subject Device Apyx Plasma/RF HP | Primary Predicate Device Renuvion/J-Plasma Precise Open HP (K183610 & K170188) |
|---|--|--|
| Indications for Use | <p>The Apyx Plasma/RF Handpiece is intended to be used with compatible electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures.</p> <p>The Apyx RF/Plasma Handpiece is compatible with the Electrosurgical Generators BVX-200H and BVX-200P owned by Apyx Medical</p> | <p>The Renuvion/J-Plasma® Precise Open Handpiece is intended to be used with compatible J-Plasma electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures.</p> <p>The Renuvion/J-Plasma® Precise Open Handpiece is compatible with electrosurgical Generators BVX-200H and BVX-200P.</p> |
| Energy Source | RF Generator; Only with Generators owned by Apyx Medical | RF Generator; Only Generators owned by Apyx Medical |
| Energy Type | Helium gas plasma; | Helium gas plasma; Monopolar coagulation |
| Electrical Currents Transmitted | 150mA – 250mA | 150mA – 250mA |
| Output | Monopolar | Monopolar |
| Device Activation | Hand activation button or optional footswitch | Hand activation button or optional footswitch |
| System Components | <p>The Apyx Plasma/RF System consists of:</p> <ul style="list-style-type: none"> ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator ▪ Gas cylinder | <p>The Renuvion/J-Plasma Precise Open System consists of:</p> <ul style="list-style-type: none"> ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator ▪ Gas cylinder |
| User Interface | Straight | Straight |
| Shaft Design & Energy Delivery Configuration | 15cm and 27cm long with a side port configuration (single or twin) and indicator lines on the shaft | 15cm and 4.4cm long with a distal port delivery configuration |



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| Feature/ Characteristic | Subject Device Apyx Plasma/RF HP | Primary Predicate Device Renuvion/J-Plasma Precise Open HP (K183610 & K170188) |
|--------------------------------|---|---|
| Shaft Outer Diameter | 3mm | 5mm |
| Electrode Configuration | Non-extendable | Extendable |
| Plasma Settings | Maximum 40 watts, 1-5 L/min gas flow | Maximum 40 watts, 1-5 L/min gas flow |
| Compatibility | Only with Electrosurgical Generators BVX-200H and BVX-200P owned by Apyx Medical | Only with Electrosurgical Generators BVX-200H and BVX-200P owned by Apyx Medical |
| Connector | Company Proprietary – per design change reflected in K183610 that establishes both pneumatic seal and electrical connection | Company Proprietary - per design change reflected in K183610 that establishes both pneumatic seal and electrical connection |

Since the predicate devices were cleared with the results of non-clinical testing, non-clinical testing was also used to support substantial equivalence for the subject Apyx Plasma/RF System. The subject device has the same indications for use, operational principle and very similar technological characteristics as the predicate devices that were cleared in K183610 & K170188 (Renuvion®/J-Plasma® Precise & Precise Open Handpieces). The conclusions drawn from the bench and pre-clinical testing demonstrate that the Apyx Plasma/RF is at least as safe and effective as the legally marketed predicate device for the same indications. Functional and mechanical verification testing demonstrate that the Apyx Plasma/RF System should perform as intended in the specified use conditions. The results of the bench, pre-clinical and ex-vivo tissue studies demonstrate that the Apyx Plasma/RF Handpiece performs comparably to the predicate device.

8. **Conclusion:**

The Apyx Plasma/RF Handpiece is a modification to the primary predicate device that was cleared in K183610 & K170188 (Renuvion/J-Plasma® Precise Open Handpiece). There are no changes to indications for use, principle of operation, mechanism of action or sterilization methods. The subject device (Apyx Plasma/RF Handpiece) like the primary predicate device (Renuvion J-Plasma® Precise Open Handpiece, K183610 & K170188) is intended for cutting, coagulation, and ablation of soft tissue and both devices utilize the same energy source (Electrosurgical Generators BVX-200H and BVX-200P) with no changes to the principle of operation.

Technological differences between the Apyx Plasma/RF Handpiece (subject device), the Renuvion/J-Plasma® Precise Open Handpiece (predicate device cleared in K183610 & K170188), and the Renuvion/J-Plasma® Precise Handpiece (predicate device cleared in

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K183610) that all share the Renuvion/J-Plasma® technology, do not raise any new concerns of safety or efficacy as:

1. Bench testing demonstrated that all three devices owned by Apyx Medical will deliver the same amount of energy to tissue at equivalent generator settings.
2. Testing utilizing porcine skin demonstrated that there is no difference in the external skin temperature profiles of these 3 devices owned by Apyx Medical.
3. Pre-clinical testing demonstrated safe internal and external tissue temperatures for the Renuvion/J-Plasma® Technology.
4. Since the energy delivered to the tissue has been demonstrated to be equivalent, it can be concluded that the histologic effect of the energy on the tissue will be equivalent between all 3 devices owned by Apyx Medical.
5. Ex-vivo tissue testing for thermal equivalency demonstrated that depth and lateral spread (i.e., average of length and width) of thermal effect measured for the Apyx Plasma/RF handpiece are equivalent to the predicate device over a range of power and flow settings which include worst-case clinical scenarios.

The subject device's safety and performance have been confirmed by results of the performance bench, ex-vivo tissue, and animal testing and the design change has gone through the design controls process to 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 tissue effects of all the subject device models (APYX-27-TP, APYX-15-TP and APYX-15-SP) are equivalent to the predicate device's effect over a range of power and flow settings that are clinically relevant.

Results of bench and animal testing demonstrate that the Apyx Plasma/RF Handpiece is as safe and effective as the predicate devices (Renuvion/J-Plasma® Precise Open Handpiece (K183610 & K170188) & Renuvion/J-Plasma® Precise Handpiece (K183610)).
