January 4, 2021

Apyx Medical Corporation (formerly Bovie Medical Corporation)
Topaz Kirlew
Vice President, Quality Assurance & Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760-4004

Re: K202880
Trade/Device Name: J-Plasma Precise FLEX Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 25, 2020
Received: September 28, 2020

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

Indications for Use

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

510(k) Number *(if known)*
K202880

Device Name
J-Plasma Precise® FLEX (APYX-500BF)

Indications for Use *(Describe)*
The J-Plasma Precise® FLEX is used for the delivery of radiofrequency energy and/or helium gas plasma (J-Plasma energy) for electrosurgical cutting, coagulation, and ablation of soft tissue. It is intended for use with a grasper during minimally invasive surgical procedures.

The J-Plasma Precise® FLEX is compatible with Apyx Medical electrosurgical generators.

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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Apyx MEDICAL

510(k) Summary K202880

1. General Information

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Email: Topaz.Kirlew@apyxmedical.com

Date Prepared: December 4, 2020

Trade Names (Model Number):
J-Plasma Precise® FLEX Handpiece
(APYX-500BF)

Common Name: Electrosurgical Handpiece

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

Predicate Device(s):
Predicate Device
Bovie J-Plasma Precise® Flex (K170777)

2. Indications for Use

The J-Plasma Precise® FLEX is used for the delivery of radiofrequency energy and/or helium gas plasma (J-Plasma energy) for electrosurgical cutting, coagulation, and ablation of soft tissue. It is intended for use with a grasper during minimally invasive surgical procedures.

The J-Plasma Precise® FLEX is compatible with Apyx Medical electrosurgical generators.

3. Device Description

The J-Plasma Precise® Flex Handpiece is a sterile, single use electrosurgical (monopolar) device intended to be used in conjunction with compatible generators for the delivery of radiofrequency ("RF") energy and/or helium gas plasma for electrosurgical cutting, coagulation, and ablation of soft tissue. It is intended for use with a grasper during minimally invasive surgical procedures. The handpiece has one configuration, model # APYX-500BF. The compatible Generators operate at an adjustable power of up to 40 W (expressed as 0-100% where 100% is 40 W) 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 J-Plasma Precise® Flex Handpiece has an extendable electrode (blade) in the tip to generate helium plasma. The tip is controlled by the user via graspers to actuate (extend and retract) the blade. The handpiece comes with an Introducer that allows for more control of the tip when introducing and removing the distal end to and from the cannula. The handpiece has a flexible, seamless cable that can be advanced with graspers through the cannula during minimally invasive surgical procedures. The handpiece is activated by the footswitch. The J-Plasma Precise® Flex System with all components and accessories is depicted in Figure 1 below:

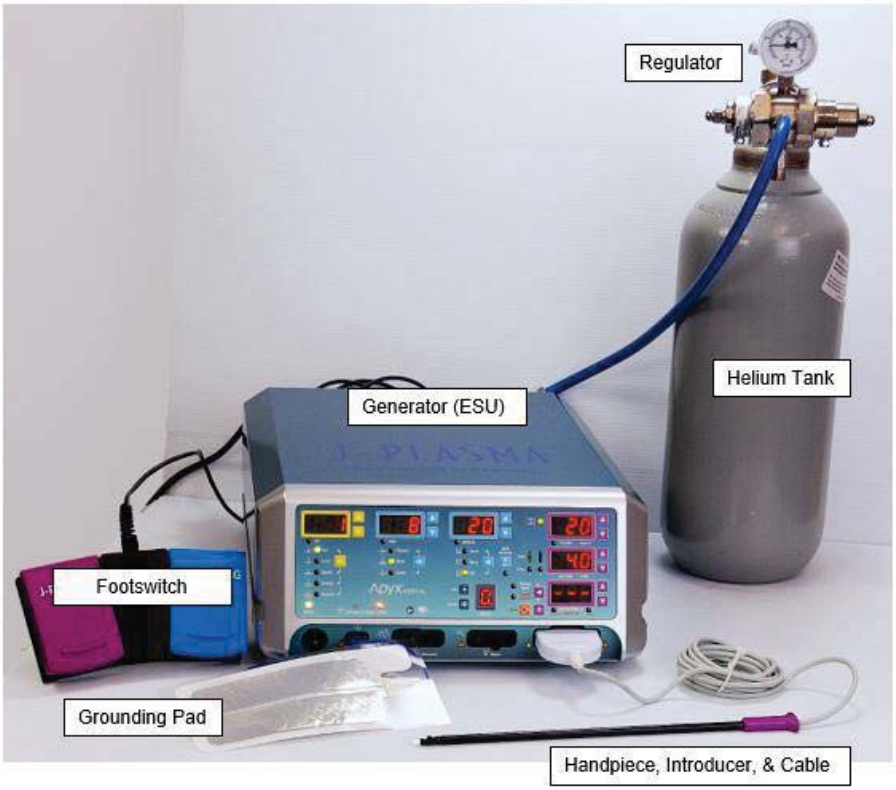

Figure 1: J-Plasma Precise® FLEX System

4. Technological Characteristics

The J-Plasma Precise® Flex Handpiece is a modification to the predicate device that was cleared in K170777 (Bovie J-Plasma Precise® Flex Handpiece). There are no changes to intended use, indications for use, operational principles, energy type, tissue treatment effects, performance specifications, electrosurgical modes, output power waveforms, maximum power settings, and plasma settings that change the energy delivered to the tissue.

The J-Plasma Precise® Flex Handpiece, as compared to the predicate device (K170777), has only the following differences in technological characteristics:

- Blade actuation, extension, and retraction is now in the distal end of the device
- Blade configuration will now extend a maximum of 5 mm
- Seamless, working length of the cable
- Addition of the Introducer, as a tip gasping aid/accessory
- Updated One-Wire Programmability for compatibility with the upgraded APYX-JS3/RS3 (Upgrades cleared under K192867)

The J-Plasma Precise® Flex Handpiece with its components is pictured below in Figures 2 and 3:

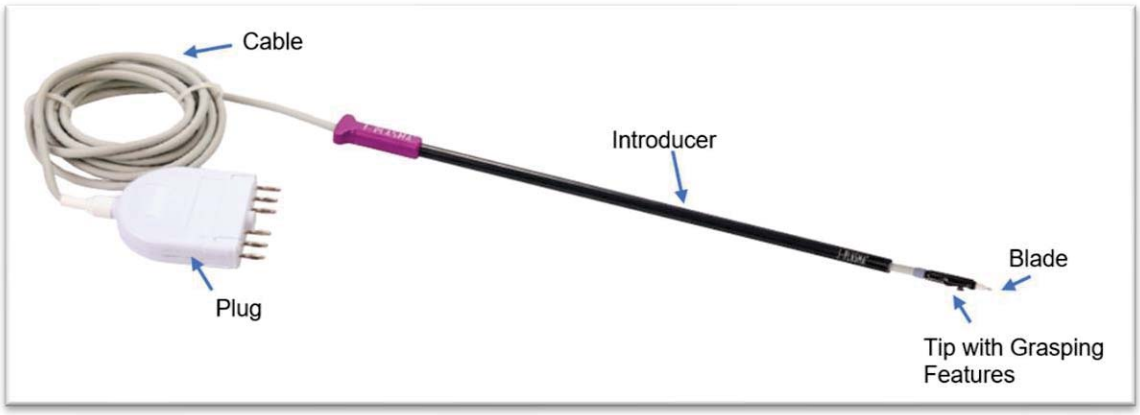

Figure 2: J-Plasma Precise® FLEX (Subject Device)

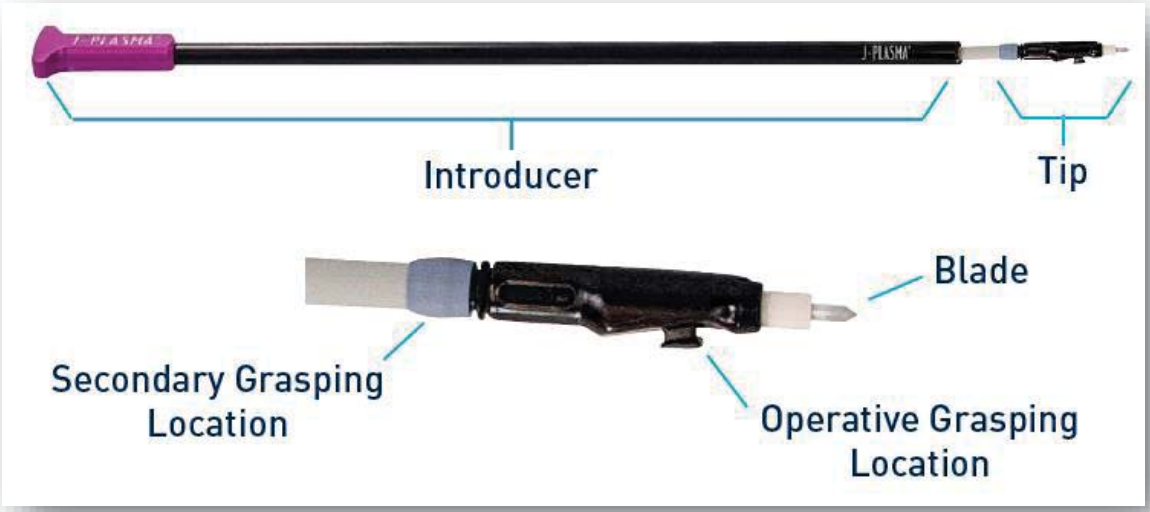

Figure 3: J-Plasma Precise® FLEX Introducer, Tip Configuration, and Grasping Features (Subject Device)

Results of verification and validation testing demonstrate that the J-Plasma Precise® Flex Handpiece is equivalent in safety and effectiveness to the predicate device, as described below.

5. Performance Data

a. Bench Testing

All testing protocols performed on the subject device, J-Plasma Precise® Flex Handpiece, were 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. Both the predicate and the modified subject device are designed by the same manufacturer, Apyx Medical (formerly Bovie Medical). The test methodology and acceptance criteria were developed from the same standards and following Apyx Medical's Design and Development procedures, in compliance with the Design and Development requirements of 21 CFR 820.30. The testing performed are summarized in table below.

b. Tissue Thermal Effect Equivalency Test

An ex-vivo study was conducted on several tissue types (i.e., muscle, liver, kidney) to compare the tissue thermal effect of the J-Plasma Precise® Flex and the predicate device. The quantitative results of this testing demonstrated that the tissue effects the subject device is equivalent to the predicate device's effect over a range of power and flow settings that are clinically relevant. This ex-vivo testing is summarized in the table below.

Test	Objective	Result
Mechanical Verification & Functionality	Verify Mechanical functionality of the J-Plasma Precise® Flex	Mechanical functionality requirements were all met.
Tissue Effect (Plasma Activation)	Verify that the tissue effects for Plasma Activation are similar between the subject device and the Predicate device (K170777) using 3 different tissue types (Muscle, Kidney & Liver)	The depth and lateral spread (i.e. average length and width) of thermal tissue effects were demonstrated to be equivalent between the subject device and Predicate device across all tissue types and J-Plasma energy settings.
Tissue Effect (Monopolar Coagulation)	Verify that the tissue effects of the subject device and the Predicate device (K170777) are the same for Monopolar Coagulation using 3 different tissue types (Muscle, Kidney & Liver)	The depth and lateral spread (i.e. average length and width) of thermal tissue effects were demonstrated to be equivalent between the subject device and Predicate device across all tissue types and Monopolar Coagulation energy settings.

c. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the J-Plasma Precise® Flex. The handpiece complies with the ANSI/AAMI/IEC 60601-1:2005/(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 J-Plasma Precise® Flex was determined to be in conformance with these standards.

6. Biocompatibility Testing

The biocompatibility evaluation for the J-Plasma Precise® Flex 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 ISO 10993-1 Fifth edition 2018-08 standard, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process”.

The J-Plasma Precise® Flex 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.

7. Substantial Equivalence

Feature / Characteristic	Bovie J-Plasma Precise Flex (Predicate Device) K170777	J-Plasma Precise FLEX (Subject Device)
Indications for Use	The Bovie J-Plasma Precise® Flex Handpiece is used for the delivery of radiofrequency energy and/or a helium gas plasma for electrosurgical cutting, coagulation, and ablation of soft tissue. It is intended for use with grasping instruments during minimally invasive surgical procedures. The Bovie J-Plasma Precise Flex Handpiece is compatible with Bovie Ultimate Generators BVX-200H and BVX-200P.	The J-Plasma Precise® FLEX is used for the of radiofrequency energy and/or helium gas plasma (J-Plasma energy) for electrosurgical cutting, coagulation, and ablation of soft tissue. It is intended for use with a grasper during minimally invasive surgical procedures. The J-Plasma Precise® FLEX is compatible with Apyx Medical electrosurgical generators.
Procedures	Laparoscopic or minimally invasive surgical procedures	Same
Energy Source	Apyx Generator	Same
Energy Type	Monopolar RF energy via Helium Plasma (helium facilitates the use of low current RF waveform)	Same
Output	Monopolar	Same
Plasma settings	Maximum 40 watts, 1-5 lpm gas flow	Same
Plasma Activation Tissue Effect	Same	Same
Monopolar Coagulation Mode	Yes	Same
Monopolar Coagulation Settings	Maximum 120 watts, 1-5 lpm gas flow	Same
Monopolar Coagulation Tissue Effect	Same	Same
System Components	The Bovie J-Plasma Precise Flex System consists of: ▪ Apyx Medical (formerly Bovie Medical) Generator ▪ Disposable handpiece ▪ Foot pedal ▪ Power cord ▪ Gas regulator ▪ Gas cylinder	Same
User Interface	Footswitch activation and generator buttons and displays.	Same
Connector	Company Proprietary Plug Connector involving 6 electrical	Same

Feature / Characteristic	Bovie J-Plasma Precise Flex (Predicate Device) K170777	J-Plasma Precise FLEX (Subject Device)
	pins and 1 pneumatic connection in the center to provide helium gas	
Shaft Design	Flexible	Same
Shaft Outer Diameter	8 mm	Same
Total Distance from Tip to Plug	3,251.2 mm total distance from tip to the plug	Same
Tip Configuration	Extendable Blade or Needle	Extendable Blade
Blade Extension	Maximum 10 mm	Maximum 5 mm
Blade Width x Thickness	1.6 mm x 0.4 mm	1.8 mm x 0.4 mm
Tip Protector	Ceramic nozzle	Same
Blade Actuation	Proximal Actuation	Distal Actuation
Device Activation	Footswitch activation only, no hand activation	Same
Grasping Feature	Yes	Same
Tip grasping aid/accessory	None	Introducer
Generator Compatibility	Compatible Bovie Medical Electrosurgical Generators	Compatible Apyx Medical (formerly Bovie Medical) Electrosurgical Generators
One-Wire Proximal Chip	ETO Sterilizable	Same
Biocompatibility Materials	All patient contacting materials are biocompatible	Same
Sterility	Single-use disposable sterile handpieces	Same
Electrical Safety	Complies with IEC Electrical Safety Standards: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Same

The subject device has the same indications for use, operational principle, and technological characteristics as the predicate device. The conclusions drawn from the bench and pre-clinical testing demonstrate that the J-Plasma Precise® Flex Handpiece is substantially equivalent in terms of safety and effectiveness to the legally marketed predicate device for the same indications. Functional and mechanical verification testing demonstrate that the J-Plasma Precise® Flex Handpiece performs as intended in the specified use conditions.

8. Conclusion

The subject device, J-Plasma Precise® FLEX, has the same intended use, indications for use, operational principles, energy type, tissue treatment effects, performance specifications, electrosurgical modes, output power waveforms, maximum power settings, and plasma settings as the originally designed predicate device (Bovie J-Plasma Precise® Flex, K170777).

The technological differences between the subject and predicate device are the transfer of the blade actuation to the tip to create a seamless design of the cable, a reduction of the maximum blade length from 10 mm to 5 mm, the addition of an introducer as a tip grasping aid, and an updated one-wire programmability for compatibility with the upgraded APYX-JS3/RS3 (these generator upgrades were cleared under K192867). The subject device and the predicate device operate in a similar manner with the same range of energy settings; the modifications explained above accommodates the users' preferences and enhances the stability of the device. Therefore, there are no differences that would raise new or different questions regarding safety or effectiveness, as the subject device and the predicate device operate in a similar manner with the same range of tissue treatment energy parameters.

The subject device's safety and performance have been confirmed by the results of the performance bench testing and the design change has gone through the design controls process and verification and validation testing to demonstrate that the device is as safe and effective as the predicate device (Bovie J-Plasma Precise® Flex, K170777).