March 12, 2019

Bovie Medical Corporation
Topaz Kirlew
Executive Director of QA & RA
5115 Ulmerton Road
Clearwater, Florida 33760

Re: K183610
Trade/Device Name: Renuvion/J-Plasma Precise Handpiece and Renuvion/J-Plasma Precise Open Handpieces
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 11, 2019
Received: January 15, 2019

Dear Dr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.03.12 13:26:07 -04'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K183610

Device Name
The Renuvion®/J-Plasma® Precise Handpiece and The Renuvion®/J-Plasma® Precise Open Handpiece

Indications for Use *(Describe)*
The Renuvion®/J-Plasma® Precise Handpiece is intended to be used with compatible J-Plasma 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 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. The Renuvion®/J-Plasma® Precise Precise Open® Handpieces are compatible with electrosurgical Generators BVX-200H, and BVX-200P.

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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Submitted by: Bovie Medical Corporation
5115 Ulmerton Road Clearwater, Florida 33760 -4004
United States of America

Contact Person: Rubiela Maldonado
Regulatory Affairs Manager
Phone: (727) 803-8508
Fax: (727) 803-4491

Submission Correspondent: Topaz Kirlew
VP, Quality Assurance & Regulatory Affairs
Phone: (727) 803-8617
Email: topaz.kirlew@apyxmedical.com

Date Prepared: December 21, 2018

Trade Name: **Renuvion®/J-Plasma® Precise Handpiece and Precise Open Handpiece**

Common Name: Electrosurgical Handpiece

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

Predicate Devices: Bovie J-Plasma Handpiece K151325 &
Bovie J-Plasma Precise Open K170188

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 gas plasma for cutting, coagulation and ablation of soft tissue during open and laparoscopic surgical procedures.

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

Device Description Renuvion/J-Plasma Handpieces (J-Plasma Precise and Precise Open):

The Renuvion/J-Plasma Handpieces are sterile, single use electrosurgical accessories 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 Handpieces are available with a retractable cutting blade tip for excising tissue. The blade tip serves as an electrode to generate helium plasma.

The Renuvion/J-Plasma Precise devices are available in 15cm, 27cm and 33cm lengths for use in laparoscopic or open surgical procedures. The 27cm and 33cm are standard lengths for laparoscopic instruments and are compatible with standard 5mm trocars.

The Renuvion/J-Plasma Precise Open devices are available in 44mm and 150mm for used in open surgical procedures.

Intended Use & Technological Characteristics

The handpieces have the same intended use as the predicate devices. There are no technological differences or changes to the principle of operation or to the method of application. There are no changes to sterilization methods.

The design of Handpieces compared to the predicate devices are identical except for the following differences:

- The plug connector to the generator is dimensioned so that it will establish a pneumatic seal connection before an electrical connection (pins shortened, and O-ring added to replace silicone seal).
- Reduced insertion/extraction force to plug/unplug the device to/from the generator.

Performance Data

Performance testing to assure that the Renuvion/J-Plasma Precise and Precise Open Handpieces met performance requirements were performed and are summarized in the following table:

Test	Objective
Mechanical & Electrical Verification and Functionality	Verify the mechanical and electrical functionality of the handpiece ▪ Pneumatic Testing ▪ Electrical Continuity test ▪ Perform Cable Flexure / Tension Test ▪ Connector Dielectric Strength Test ▪ Mold Stress Test ▪ Free-fall Drop Test ▪ Insertion/Extraction Integrity
Usability Evaluation	The purpose of this protocol is to verify and validate the usability of the J-Plasma Pistol Grip Handpiece as it relates to safety.

Biocompatibility Testing

The biocompatibility evaluation for the Renuvion/J-Plasma Handpieces was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of evaluations included the following testing:

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

The Renuvion/J-Plasma handpieces are 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. Due to the redesign of the plug connector, changes on materials were made to two patient contacting components, flow tube coupler and O-ring. Biocompatibility verification testing was satisfactorily conducted for these components.

Conclusion

There is no difference between the predicate predicates, Precise J-Plasma handpiece and Precise Open handpiece and the Subject devices in terms of intended use, principle of operation, and the technology used for device performance. There is no new technology and there are no differences that would raise new or different questions of safety or efficacy.

Verification and validation testing of the Renuvion/J-Plasma handpieces demonstrate that the devices perform as intended.