February 23, 2023

Apyx Medical Corporation
Mark Evans
Sr. Premarket Regulatory Affairs Specialist
(formerly Bovie Medical Corporation)
5115 Ulmerton Road
Clearwater, Florida 33760-4004

Re: K223262
Trade/Device Name: Renuvion® APR Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 27, 2023
Received: January 27, 2023

Dear Mark Evans:

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,

Jessica Carr -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223262

Device Name
Renuvion® APR Handpiece

Indications for Use *(Describe)*
The Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue.

The Renuvion® APR Handpiece is indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.

The Renuvion® APR Handpiece is intended to be used with compatible electrosurgical generators 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.

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
5115 Ulmerton Road Clearwater, Florida 33760 -4004
United States of America

Establishment Registration #:
3007593903

Contact Person:
Mark D. Evans, Sr. Premarket Regulatory Affairs Specialist
5115 Ulmerton Road
Clearwater, Florida 33760-4004
United States of America
Phone: (856) 524-5037
Email: mark.evans@apyxmedical.com

Date Prepared:
October 21st, 2022

Trade Names (Model Numbers):
Renuvion® APR 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 and Reference Devices:
Predicate Device
Renuvion® APR Handpiece (K220970)

Reference Device
Ellusa Bipolar Wands (K202558)

Proposed Indications for Use:

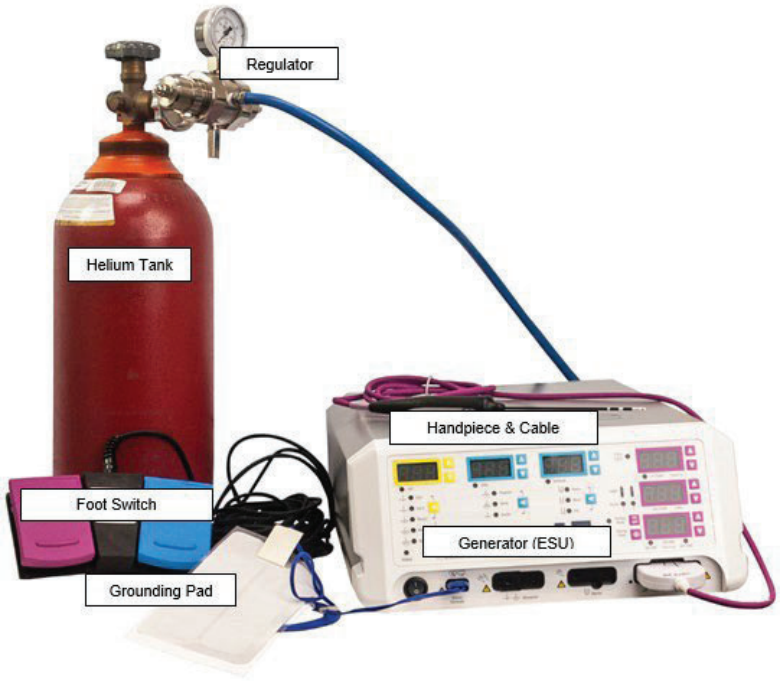
Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue.

The Renuvion® APR Handpiece is indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.

The Renuvion® APR Handpiece is intended to be used with compatible electrosurgical generators owned by Apyx Medical.

2. Device Description and Technological Characteristics:

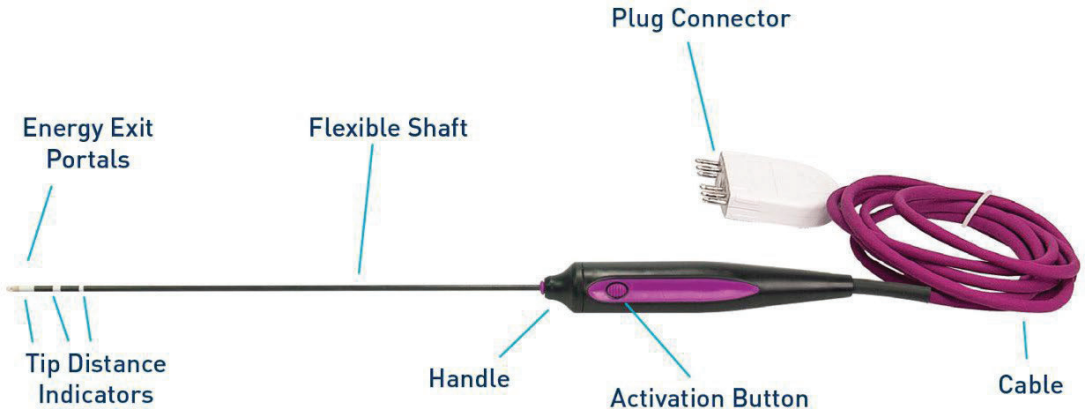
The **Renuvion® APR System** with all components and accessories is shown in the picture below. The system is comprised of a compatible electrosurgical generator, a sterile, single use handpiece, and a supply of helium gas. Additional accessories include a gas regulator, grounding pad and optional footswitch.



The **Renuvion® APR Handpiece** is a sterile, single-use electrosurgical (monopolar) device intended to be used in conjunction with compatible electrosurgical generators. 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 passes over the energized electrode, a helium plasma is generated which delivers thermal energy to soft tissue for the purposes of cutting, coagulation/contraction, or ablation.

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 Renuvion APR Handpiece is pictured below.



3. Performance Data:

a. Bench Testing

N/A; no design modifications were made to the commercially available Handpiece cleared under K220970.

b. Electrical Safety and Electromagnetic Compatibility (EMC)

N/A; no design modifications were made to the commercially available Handpiece cleared under K220970.

c. Biocompatibility Testing

N/A; no design modifications were made to the commercially available Handpiece cleared under K220970.

4. Pre-Clinical & Ex-Vivo Studies:

Ex vivo tissue testing that included liver, kidney, and muscle tissues to measure the coagulative effect of the device on tissue was previously provided in 510(k) submission K191542 is presented below in summary format. Apyx Medical conducted a GLP Acute Porcine Study to assess thermal effects of the subject device use in subcutaneous and connective tissue. The data demonstrated the thermal effects of the device on subcutaneous soft tissues.

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5. Clinical Studies:

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

6. Substantial Equivalence:

Feature/ Characteristic	Subject Device	Predicate Device	Reference Device
	Renuvion® APR Handpiece[1]	**Apyx Plasma/RF Handpiece (K220970)**	**Ellusa Bipolar Wands (K202558)**
Classification	Class II	Class II	Class II
Regulation Name and Product Code:	Electrosurgical cutting & coagulation device and accessories, GEI	Electrosurgical cutting & coagulation device and accessories, GEI	Electrosurgical cutting & coagulation device and accessories, GEI
Indications for Use Statement	Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma **where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue.** The Renuvion® APR Handpiece is indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.	The Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures. The Renuvion® APR Handpiece is indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.	The Ellusa Bipolar Wands are intended for use by a physician familiar with bipolar coagulation with electrosurgery where coagulation/contraction of soft tissue is needed.

[1] The **Bold text** represents the modified wording.

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510(k) Summary

Feature/ Characteristic	Subject Device	Predicate Device	Reference Device
	Renuvion® APR Handpiece[1]	**Apyx Plasma/RF Handpiece (K220970)**	**Ellusa Bipolar Wands (K202558)**
	The Renuvion® APR Handpiece is intended to be used with compatible electrosurgical generators owned by Apyx Medical.	The Renuvion® APR Handpiece is intended to be used with compatible electrosurgical generators owned by Apyx Medical (specifically BVX-200H, BVX-200P, APYX-200H, APYX-200P, APYX-RS3, and APYX-JS3).	
Energy Source	RF Generator, only Generators owned by Apyx Medical	RF Generator, only Generators owned by Apyx Medical	RF Generator
Energy Type	Radio frequency (RF) Energy and Helium Gas	Radio frequency (RF) Energy and Helium Gas	Radio frequency (RF) Energy
System Components	The Apyx Plasma/RF System consists of: ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator ▪ Gas cylinder	The Apyx Plasma/RF System consists of: ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator ▪ Gas cylinder	The Ellusa RF System consists of: ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord
Design & Energy Delivery Configuration	15cm and 27cm long shaft with a side port configuration (single or twin) and indicator lines on the shaft	15cm and 27cm long shaft with a side port configuration (single or twin) and indicator lines on the shaft	11cm to 40cm long, with Ball Tip, Standard, or Hex Blade Tip configuration
Shaft Outer Diameter	3mm	3mm	1.2mm to 6mm

7. Substantial Equivalence Determination

The subject and predicate devices are identical. No design modifications were made to the predicate for this new 510(k) submission. The only change is to modify the indications for use of the subject device to include “where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue.”

The reference device received FDA clearance for the coagulation/contraction of soft tissue by performing ex vivo tissue testing that included liver, kidney, and muscle tissues to measure the coagulative effect of the device on tissue. Apyx Medical conducted the same ex vivo tissue testing using the Renuvion APR handpiece on liver, kidney, and muscle tissues at 20%, 50%, and 100% power and 1, 3, and 5 Lpm gas flow rate. Measurements of lateral spread and depth of thermal effect were characterized under histological examination.

Additionally, to support use in subcutaneous tissue, the subject device was tested in an in vivo acute porcine study at 60-80% power and 1.5 Lpm gas flow rate. The handpiece was moved continuously at a rate of 1 cm/sec while depositing the energy subcutaneously in the flank region of the animal. Depth of thermal effect in subcutaneous tissue was measured and analyzed via histology. The results of this testing supports the addition of “contraction” and “subcutaneous tissue” to the indication for use statement of the subject device.

Conclusion:

The subject of this submission is the modifications to the general intended use for the Renuvion APR Handpiece. The proposed changes to the indications for use are supported by ex vivo and in vivo tissue testing that demonstrates the coagulative tissue effects. The commercially available Renuvion® APR handpiece is safe and effective, and the modifications to the indications for use do not raise any new questions of safety or effectiveness compared to the predicate device.