July 15, 2022

Apyx Medical Corporation(formerly Bovie Medical Corporation)
Priscilla Herpai
Global Director of Regulatory
5115 Ulmerton Road
Clearwater, Florida 33760-4004

Re: K220970
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: June 10, 2022
Received: June 13, 2022

Dear Priscilla Herpai:

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,

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)*
K220970

Device Name
Renuvion® APR Handpiece

Indications for Use *(Describe)*
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 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).

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

1. General Information:

Submitted by:	Apyx Medical Corporation 5115 Ulmerton Road Clearwater, Florida 33760 -4004 United States of America
Establishment Registration #:	3007593903
Submitter FAX Number:	(727) 322-4465
Contact Person:	Priscilla Herpai, Global Regulatory Affairs Director 5115 Ulmerton Road Clearwater, Florida 33760 -4004 United States of America Phone: (610) 533-7984 Email: priscilla.herpai@apyxmedical.com
Date Prepared:	April 1, 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 Devices:	Predicate Device Apyx Plasma/RF Handpiece (K191542)

2. Proposed Indications for Use:

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 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).

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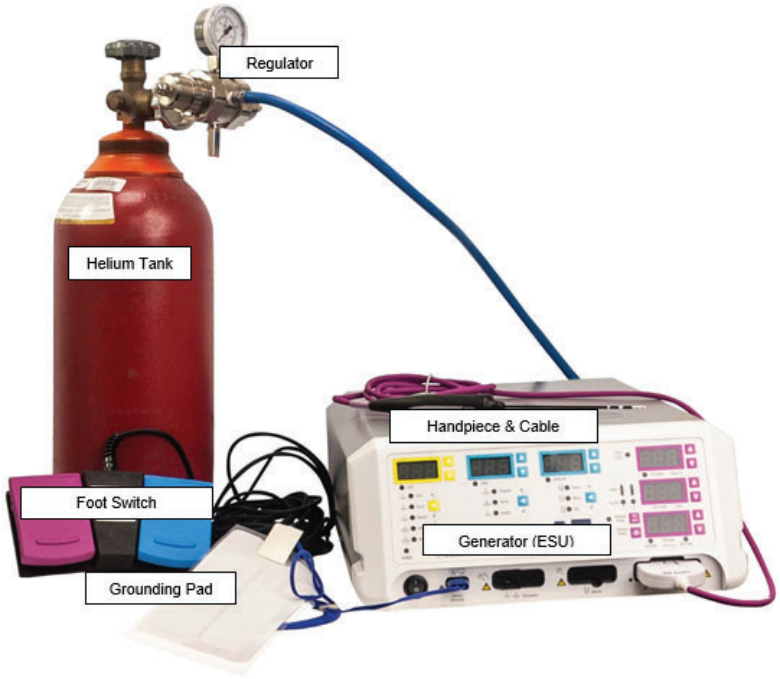
3. Device Description:

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 for soft tissue cutting, coagulation or ablation.

The Renuvion® APR 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 Renuvion® APR System with all components and accessories is show in the picture below.



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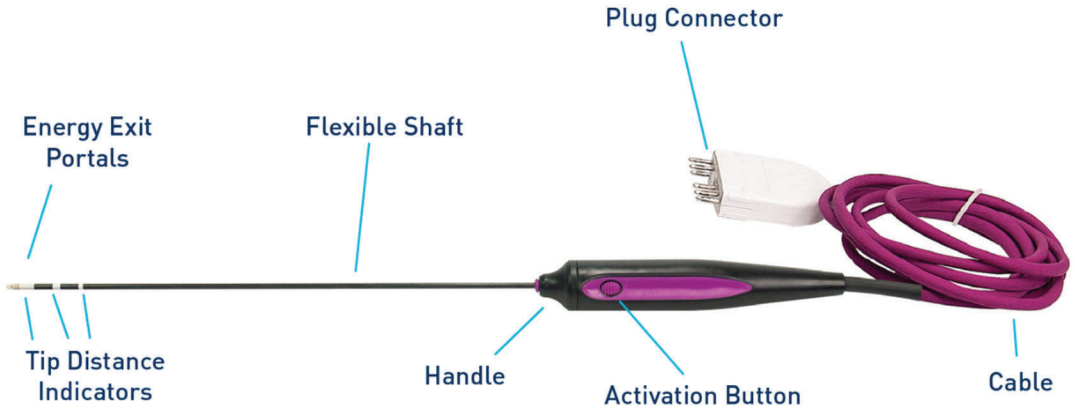
4. Technological Characteristics:

The Renuvion APR Handpiece with its components is pictured below.



5. Performance Data:

a. Bench Testing

N/A; no modifications were made to the commercially available Handpiece cleared under K191542.

b. Electrical Safety and Electromagnetic Compatibility (EMC)

N/A; no modifications were made to the commercially available Handpiece cleared under K191542.

c. Biocompatibility Testing

N/A; no modifications were made to the commercially available Handpiece cleared under K191542.

6. Pre-Clinical & Ex-Vivo Studies:

N/A; no modifications were made to the commercially available product cleared under K191542.

7. Clinical Studies:

Performance was assessed in a prospective, multi-center, evaluator-blinded study of 65 adults, age 35-65 years. The bilateral treatment area included the tissue of the neck (to the posterior border of the sternocleidomastoid muscle) and the submental area. After infusion of tumescent anesthesia, three incisions (2 periauricular and 1 submental) were used to allow tunneling/undermining with a cannula followed by treatment with Renuvion APR handpiece, using 4-6 treatment passes at settings of 70% power, 1.5 LPM of helium flow, and an average movement speed of approximately 5.5 cm/s.

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The primary effectiveness endpoint was response rate at Day 180, where a responder was defined as correct identification of the “after” images by at least 2 of 3 blinded Independent Photographic Reviewers. The responder rate was 82.5%.

The most common adverse events were edema, temporary sensory nerve injury, ecchymoses, erythema, crepitus, pain/tenderness, nodules, temporary motor nerve injury, and pruritus.

Primary Effectiveness Endpoint: The primary effectiveness endpoint was improvement in the appearance of lax tissue in the neck and submental region at 180-days as determined by 2 out of 3 blinded Independent Photographic Reviewers through assessment of 2D photography images ***The observed proportion of subjects achieving the primary effectiveness endpoint and demonstrating an improvement in the appearance of lax skin in the neck and submental region was 82.5% (52/63) (97.5% one-sided lower CL=70.9% p<.0001).***

Primary Safety Endpoint: The primary safety endpoint was the proportion of subjects with none-to-moderate pain at 7 days, on a Numeric Rating Scale (NRS) through the 7-day follow-up visit. The baseline NRS score was 0 in 100% of subjects. ***The observed proportion of subjects achieving the primary safety endpoint was 96.9% (62/64) (97.5% one-sided lower CL=89.2% p<.0001).***

Conclusion: The totality of the data demonstrates benefit to subjects in the improvement of the appearance of lax tissue in the neck and submental region. The primary effectiveness endpoint for this study was achieved at 82.5%. The primary safety endpoint was achieved at 96.9%.

8. Substantial Equivalence:

Feature/ Characteristic	Subject Device Renuvion® APR Handpiece	Predicate Device Apyx Plasma/RF Handpiece (K191542)	Comments
Classification	Class II	Class II	Identical
Regulation Name and Product Code:	Electrosurgical cutting & coagulation device and accessories, GEI	Electrosurgical cutting & coagulation device and accessories, GEI	Identical
Indications for Use	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 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).	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 RF/Plasma Handpiece is compatible with the Electrosurgical Generators BVX-200H and BVX-200P owned by Apyx Medical	Expanded indication to support additional claim. See Substantial Equivalence Discussion.

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Feature/ Characteristic	Subject Device Renuvion® APR Handpiece	Predicate Device Apyx Plasma/RF Handpiece (K191542)	Comments
Energy Source	RF Generator, only Generators owned by Apyx Medical	RF Generator, only Generators owned by Apyx Medical	Identical
Energy Type	Helium gas plasma	Helium gas plasma	Identical
Electrical Currents Transmitted	150mA – 250mA	150mA – 250mA	Identical
Output	Monopolar	Monopolar	Identical
Device Activation	Hand activation button or optional footswitch	Hand activation button or optional footswitch	Identical
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	Identical
User Interface	Straight	Straight	Identical
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 27cm long with a side port configuration (single or twin) and indicator lines on the shaft	Identical
Shaft Outer Diameter	3mm	3mm	Identical
Electrode Configuration	Non-extendable	Non-extendable	Identical

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Feature/ Characteristic	Subject Device	Predicate Device	
	Renuvion® APR Handpiece	Apyx Plasma/RF Handpiece (K191542)	Comments
Plasma Settings	Maximum 40 watts, 1-5 L/min gas flow	Maximum 40 watts, 1-5 L/min gas flow	Identical
Compatibility	Only with Electrosurgical Generators owned by Apyx Medical	Only with Electrosurgical Generators owned by Apyx Medical	Identical
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	Identical

Substantial Equivalence Determination

Because the subject device is the predicate device and no modifications were made to the subject device for this new 510(k) submission, there is no question of substantial equivalence in technological performance or material characterization.

The only change is to expand the indication for use to add a specific claim related to the treatment of lax skin. Data to support this expanded indication was generated through a prospective IDE Clinical study approved by FDA (G190152). The results of the clinical trial support the expanded Indications for Use.

The clinical study VP-1902, a prospective, multi-center, evaluator-blinded study evaluating the safety and effectiveness of the Renuvion APR Handpiece to improve the appearance of lax tissue in the neck and submental region, was conducted to support efficacy of the treatment and to demonstrate substantial equivalence in safety compared to the predicate device.

As such, the results provide evidence to demonstrate that the expanded indication does not raise any new safety questions. The efficacy results support the claim of improvement in the appearance of lax skin.

9. Conclusion:

The Renuvion® APR Handpiece is identical in terms mechanism of action and sterilization methods to the predicate device, Apyx Plasma/RF Handpiece (K191542).

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510(k) Summary

1. The only difference between the subject and predicate devices is the addition of a specific indication for use.

2. The Renuvion APR Handpiece's safety and performance in the indications for use have been confirmed by results of the clinical study, IDE Study G190152.

3. There are no issues that would raise new or different questions of safety or effectiveness and the benefits of the Renuvion APR handpiece outweigh the risks of its intended use.

4. The clinical data presented in this 510(k) supports the safety of the subject device. Additionally, the clinical data further supports the subject device performs as intended and in accordance with its specifications.

The Renuvion® APR handpiece is as safe and effective and is substantially equivalent to the predicate device.