May 8, 2023

Apyx Medical Corporation
Angela Huber
Global Director of Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760-4004

Re: K230272
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

Dear Angela Huber:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 27, 2021. Specifically, FDA is updating this SE Letter due to a formatting error in which the K-number appears as 2K230272 in the header of page 2 as an administrative correction.

Please note that the 510(k) sub mission was not re-reviewed. For questions regarding this letter please contact Long Chen, OHT4: Office of Surgical and Infection Control Devices, 301-796-6389, or Long.Chen@fda.hhs.gov.

Sincerely,

Mark Trumbore, Ph.D.

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.05.08 08:19:04 -04'00'

For Long Chen, Ph.D.
Acting 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

April 27, 2023

Apyx Medical Corporation
Angela Huber
Global Director of Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760-4004

Re: K230272
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: March 31, 2023
Received: March 31, 2023

Dear Angela Huber:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.04.27 13:00:33 -04'00'

Mark Trumbore, 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)*

Device Name
Renuvion® APR Handpiece

Indications for Use *(Describe)*
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 intended for the coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring.

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 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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PRAStaff@fda.hhs.gov

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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:	Angela Huber, PhD, RAC, Global Director of Regulatory Affairs Phone: 218-343-4881 Email: angela.huber@apyxmedical.com
Date Prepared:	March 30th, 2023
Trade Name (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 Device:	**Renuvion® APR Handpiece** (K220970)
Secondary Predicate Device:	**Renuvion® APR Handpiece** (K223262)

2. 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 intended for coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring.

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.

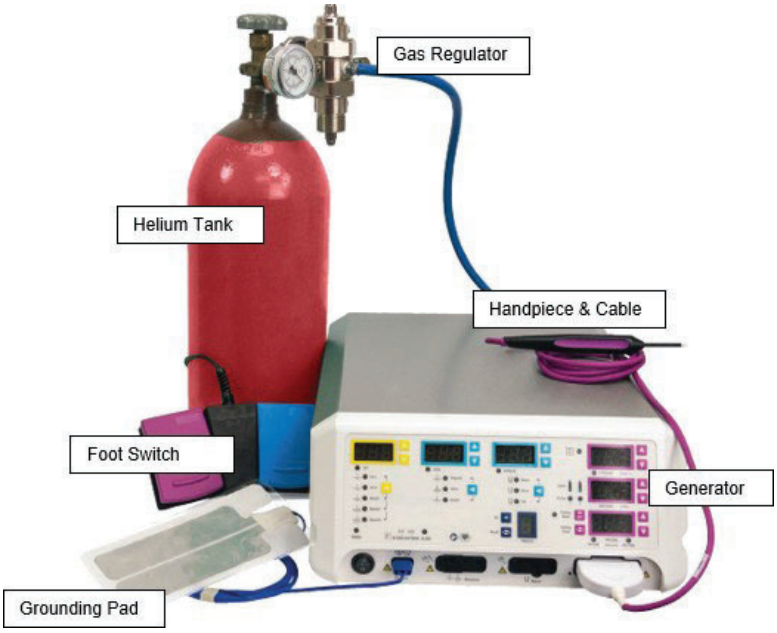
The Renuvion® APR Handpiece is intended to be used with compatible electrosurgical generators owned by Apyx Medical.

3. Device Description

The Renuvion® APR (Apyx Plasma/RF) handpiece is a sterile, single use electrosurgical (monopolar) device intended to be used in conjunction with a compatible generator for the delivery of radiofrequency energy and helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures. 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 cutting, coagulation or ablation of soft tissue during open surgical procedures. 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 L/Min. APR Handpiece has a non-extendable electrode to generate helium plasma. The handpiece is available in two different lengths: 15 cm and 27 cm. The 15 cm 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).

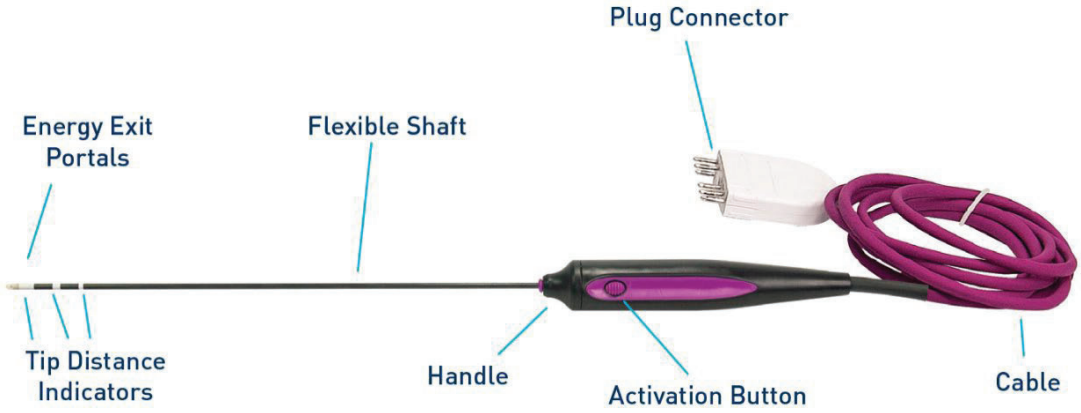
The device can also be used for percutaneous delivery of radiofrequency and helium plasma energy to coagulate subcutaneous soft tissue. The recommended settings for subcutaneous soft tissue coagulation are provided in detail in Section C.1 RECOMMENDED SETTINGS & TREATMENT PARAMETERS of the Instructions for Use.

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



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 K220970.

b. Electrical Safety and Electromagnetic Compatibility (EMC)

N/A; no modifications were made to the commercially available handpiece cleared under K220970 or generator cleared under K192867.

c. Biocompatibility Testing

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

6. Pre-Clinical & Animal Studies

No modifications were made to the commercially available handpiece cleared under K220970 and K223262. 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 and K223262. Apyx Medical conducted a GLP Acute Porcine Study to assess thermal effects of the subject device use in subcutaneous tissue. The data demonstrated the thermal effects of the device on subcutaneous soft tissues and was previously provided in 510(k) submission K191542 and K223262.

7. Clinical Performance

The Renuvion APR handpiece safety and effectiveness in the neck and submental region was assessed in IDE, G190152 (*VP-1902, A Prospective Multi-Center,*

Evaluator-Blinded Study evaluating the Safety and Effectiveness of the Renuvion APR Device to Improve the Appearance of Lax Tissue in the Neck and Submental Region).

Apyx analyzed real-world evidence gathered from 6 studies in which all procedures used Renuvion APR following liposuction. This data set includes retrospective chart reviews in 1,184 body areas (across 483 subjects in the following body areas: abdomen, arms, back, buttocks, breast/axilla, face, hips/flanks, legs, neck) followed by coagulation of the subcutaneous soft tissues with Renuvion following liposuction. These data were then compared to the adverse event rates for liposuction alone established in a published meta-analysis. This data supports the safe use of the device for its proposed indications for use.

8. Substantial Equivalence

The Renuvion APR handpiece is the predicate device; therefore all technological and performance characteristics are the same. The only difference is the addition to the indications for use.

Feature/ Characteristic	Subject Device	Predicate Device	Secondary Predicate Device	Comments
	Renuvion® APR Handpiece (K230272)	**Renuvion® APR Handpiece (K220970)**	**Renuvion® APR Handpiece (K223262)**	
Classification	Class II	Class II	Class II	Identical
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	Identical
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 intended for the coagulation of subcutaneous soft	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	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	Generally, the predicate is indicated for use during open surgical procedure or percutaneous procedures and associated surgical equipment. The modification to the intended use is to specify

	tissues following liposuction for aesthetic body contouring. 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 intended to be used with compatible electrosurgical generators owned by Apyx Medical.	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).	neck and submental region. The Renuvion® APR Handpiece is intended to be used with compatible electrosurgical generators owned by Apyx Medical.	that the handpiece is intended for the coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring.
Energy Type	Helium gas plasma	Helium gas plasma	Helium gas plasma	Identical
Electrical Currents Transmitted	150mA – 250mA	150mA – 250mA	150mA – 250mA	Identical
EnergyType Delivered	Monopolar RF energy via Helium Plasma (helium facilitates the use of low current RF waveform)	Monopolar RF energy via Helium Plasma (helium facilitates the use of low current RF waveform)	Monopolar RF energy via Helium Plasma (helium facilitates the use of low current RF waveform)	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	The Apyx Plasma/RF System consists of: ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator Gas cylinder	Identical
User Interface	Straight	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	15cm and 27cm long with a side port configuration (single or twin) and indicator lines on the shaft	Identical
Shaft Outer Diameter	3mm	3mm	3mm	Identical
Electrode Configuration	Non-extendable	Non-extendable	Non-extendable	Identical
Plasma Settings	Maximum 40 watts, 1-5 L/min gas flow	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	Only with Electrosurgical Generators owned by Apyx Medical	Identical

9. Substantial Equivalence Determination

The subject device and predicate device are identical with the exception of the modification to the intended use statement to specify that the Renuvion® APR Handpiece is intended for the coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring. Apyx was able to assess the device based on a large set of retrospective chart reviews.

No new risks were identified in the risk analysis or real-world evidence and published literature analysis. Renuvion treatment adverse events (AEs) compared to the real-world evidence gathered for the liposuction treatments in the literature review demonstrated there are no new or increased risks for Renuvion procedures following liposuction procedures compared to liposuction alone. These findings support the proposed indications for use.

10. Conclusion

The Renuvion APR is identical in terms of principle of operation, mechanism of action and sterilization methods to the predicate device, Renuvion APR (K220970 and K223262). The only difference between the subject and predicate devices is the indications for use statement. The clinical data presented in this 510(k) supports the substantial equivalence of safety and effectiveness of the subject device for the proposed indications for use. Therefore, the subject device is as safe and effective as the predicate, and the data presented supports a substantially equivalent decision.