June 9, 2023

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

Re: K230586
Trade/Device Name: Renuvion® Micro Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 15, 2023
Received: May 15, 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.09 15:33:07 -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® Micro Handpiece

Indications for Use *(Describe)*
Renuvion® Micro 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® Micro Handpiece is compatible with the Apyx One Console Generator, 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 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:	March 2, 2023
Trade Names (Model Numbers):	**Renuvion® Micro Handpiece** (APYX-10-Micro)
Common Name:	Electrosurgical Handpiece
Classification:	Class II per 21CFR 878.4400 - Electrosurgical Cutting and Coagulation Device and Accessories Product Code GEI
Primary Predicate Device:	**Renuvion® APR Handpiece** (K223262)
Secondary Predicate Device:	**Renuvion® APR Handpiece** (K230272)

2. Proposed Indications for Use:

Renuvion® Micro 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® Micro Handpiece is compatible with the Apyx One Console Generator, owned by Apyx Medical.

3. Device Description and Technological Characteristics:

5. 510(k) Summary

The **Renuvion® Micro System** with all components and accessories is show in the picture below. The system is comprised of a compatible electrosurgical generator (Apyx One Console)[1], a sterile, single use handpiece, and a supply of helium gas. Additional accessories include a digital gas regulator[2], grounding pad[3] and optional footswitch[4].

The front view of the entire system with all components and accessories is depicted in **Figure 1** below.

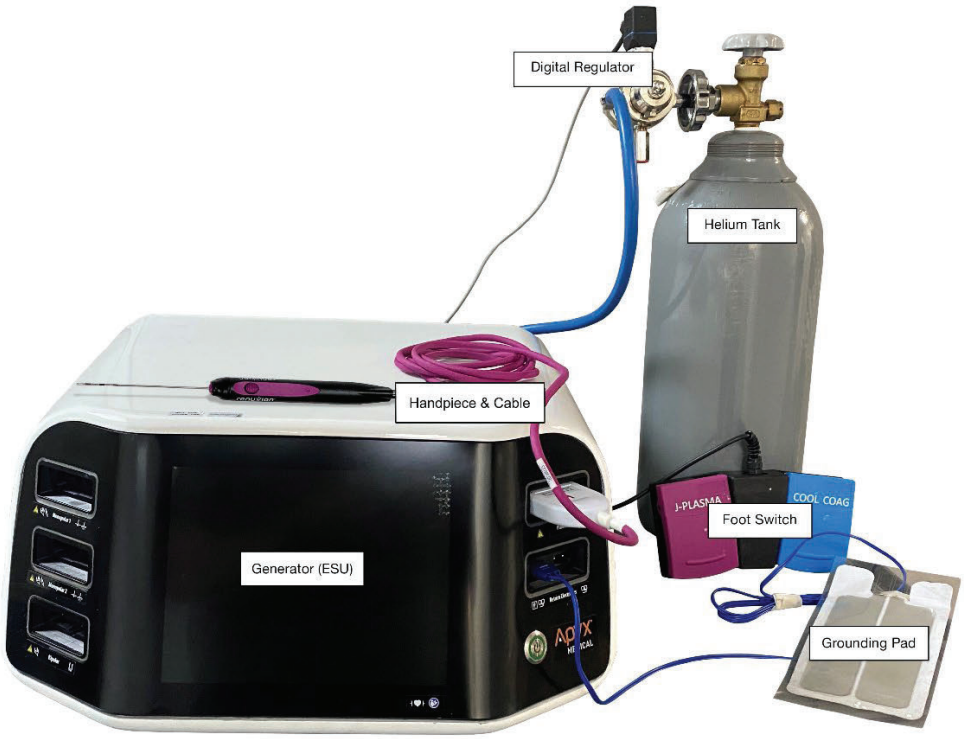

Figure 1: Front View of System

[1] 510(K) Number: K221830
[2] 510(K) Number: K221830
[3] 510(k) Number: K092761
[4] 510(K) Number: K170188

5. 510(k) Summary

The **Renuvion® Micro handpiece** is a sterile, single use electrosurgical (monopolar) device intended to be used in conjunction with the Apyx One Console Electrosurgical Generator for the percutaneous delivery of radiofrequency and helium plasma energy to soft tissue. When connected to the Apyx One Generator, the device operates at an adjustable power of up to 12 W (expressed as 0 – 30% where 30% is 12 W) and an adjustable helium gas flow of 1 – 1.5 L/Min. 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 coagulation/contraction.

The handpiece has a non-extendable electrode to generate helium plasma. The handpiece features a low-profile shaft that is 10cm in length. The distal end of the shaft and tip has a 2mm outer diameter that tapers down to 1.5mm for the remaining length of the shaft.

The Renuvion® Micro Handpiece is pictured in **Figure 2** below.

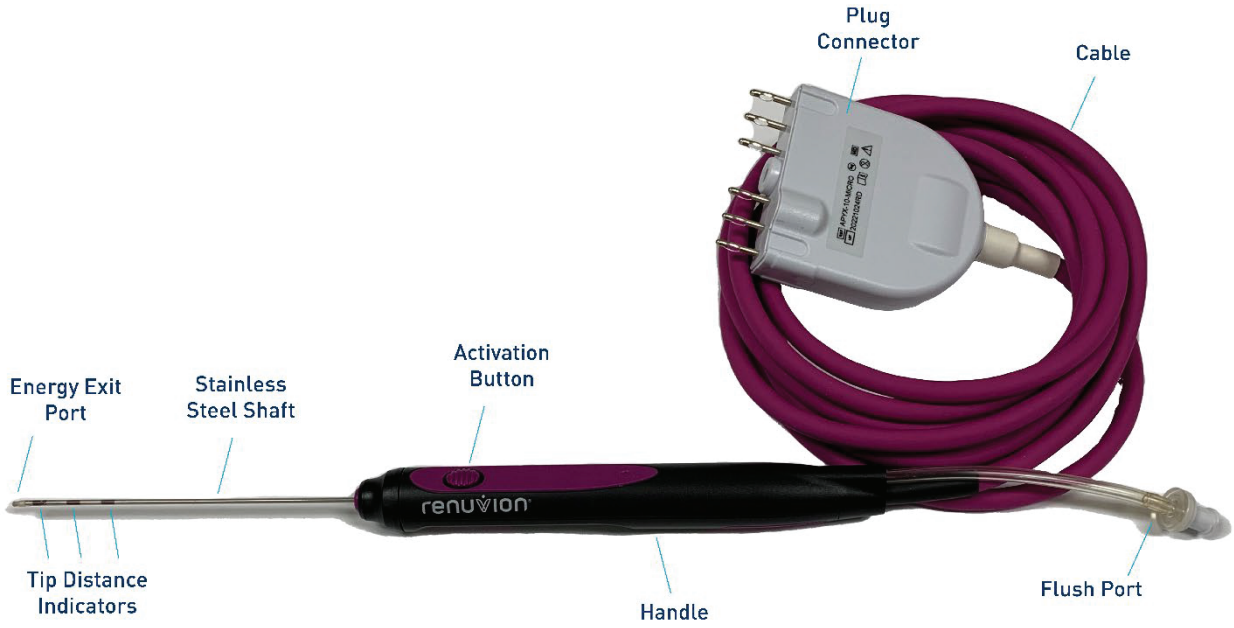

Figure 2: Renuvion® Micro Handpiece Major Components

The Renuvion® Micro Handpiece is a modification to the primary predicate device that was cleared in K223262 (Renuvion® APR Handpiece). There are no changes to the principle of operation or mechanism of action.

The Renuvion® Micro Handpiece as compared to the predicate devices has the following differences in technological characteristics to enable the smaller overall dimensional profile:

- front-port ceramic nozzle/tip, rather than predicate side-port configuration
- introduces a sterile saline flush port to assist in removing coagulum build up on the ceramic tip.
- The subject devices shaft material is stainless steel with an outer polymer layer, whereas the predicate used a polymer-based material throughout.
- The subject device maximum allowable power setting will lowered compared to the predicate, 30% power and maximum helium flow will be 1.5 L/min

4. Performance Data:

a. Bench Testing

All testing performed on the Renuvion® Micro Handpiece, hereinafter referred to as Micro Handpiece, was derived from the risk assessment in accordance with ISO 14971 which evaluated the safety and effectiveness of the design with Apyx Medical's Design and Development procedures. The test methodology and acceptance criteria were developed from the same standards and internal Design and Development procedures used for clearance of the primary predicate device.

A risk analysis was conducted using the Design Risk Analysis and Control (DRAC) for the subject device (Micro Handpiece). The risk analysis concluded that no new failure modes or risk hazards were identified as a result of the design modifications.

Performance testing to assure that the subject device met performance requirements was conducted in accordance with protocols to verify design specifications. The testing performed is summarized in the following table:

Test	Objective	Result
Mechanical Verification & Functionality	Verify Mechanical functionality of the Renuvion® Micro Handpiece	Mechanical functionality requirements met
System compatibility Testing	Verify the device, when connected to the generators (with all the components and accessories working together as a system), are working as intended and are compatible with all system components.	System compatibility requirements met
Inspectional Verification	Document parameters that can be verified through inspection of the Micro Handpiece Labeling and IFU.	Inspectional requirements met

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5. 510(k) Summary

Test	Objective	Result
Packaging Validation	Evaluate simulated (and/or real-time) aging and associated package integrity and shelf-life claims. Assess the potential for damage to the device (e.g., drop tests of the instrument in its packaging).	Packaging requirements met

b. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Renuvion® Micro System. The handpiece complies with the ANSI/AAMI/IEC 60601-1:2015/(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 Renuvion® Micro System was determined to be in conformance with these standards.

c. Biocompatibility Testing

The biocompatibility evaluation for the Micro 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 AAMI/ANSI/ISO 10993-1:2018 standard, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process". A Biological Evaluation Plan within Apyx Medical's risk management process was developed for the Micro Handpiece to determine the testing and risk assessment for the device and to develop a plan for the mitigation of risks identified.

Biocompatibility testing performed is summarized below:

Category: External Communicating Device
Contact: Tissue / Bone / Dentin
Duration of Contact: Limited < 24 hours

Test	Result
Cytotoxicity	Non-cytotoxic
Sensitization	No sensitization reaction

Irritation	Non-irritant
Acute Systemic Toxicity	Non-toxic
Material Mediated Pyrogen/Pyrogenicity	Non-pyrogenic

The design of the subject device is supported by evidence of biocompatibility verification testing to ensure the device is safe for human use. The materials used in the manufacture of the device met biocompatibility test requirements for external communicating device, Tissue/Bone/Dentin, limited duration devices.

5. Pre-Clinical & Ex-Vivo Studies:

Ex-vivo tissue testing was conducted and is summarized in the table below:

Test	Objective	Result
Thermal Tissue Effect	Evaluate the thermal effect between Renuvion Micro Handpiece (APYX-10-MICRO) against its predicate device (Renuvion APR Handpiece, 15 cm, Twin Port, APYX-15-TP).	The test device (APYX-10-MICRO) was subjected to tissue thermal testing and demonstrated an equal or less tissue thermal effect when compared to the predicate device (APYX-15-TP) on five different tissue types at different Renuvion settings.
Tissue Temperature Over 85 Degrees Celsius Comparison	Evaluate the tissue time over 85 degrees Celsius between the Renuvion Micro Handpiece (APYX-10-MICRO) and its predicate device (Renuvion APR Handpiece, 15 cm, Twin Port, APYX-15-TP) when used at the recommended setting per the IFU for coagulation/contraction of soft tissue such as subcutaneous tissues.	The test device (APYX-10-MICRO) met the acceptance criteria demonstrating that on average the device is at or above 85 degrees for greater than 45 msec. The predicate device showed similar results as a control.

6. Clinical Studies:

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

7. Substantial Equivalence:

The primary predicate and the secondary predicate are identical, with the exception of their indications for use.

Feature/ Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Renuvion® Micro Handpiece	**Renuvion® APR Handpiece (K223262)**	**Renuvion® APR Handpiece (K230272)**
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® Micro Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue. The Renuvion® Micro Handpiece is compatible with the Apyx One Console Generator, owned by Apyx Medical.	Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma 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	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

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5. 510(k) Summary

Feature/ Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Renuvion® Micro Handpiece	Renuvion® APR Handpiece (K223262)	Renuvion® APR Handpiece (K230272)
		be used with compatible electrosurgical generators owned by Apyx Medical.	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.
Energy Source	RF Generator, Apyx One Console Generator	RF Generator, Generators owned by Apyx Medical	RF Generator, Generators owned by Apyx Medical
Energy Type	Radio frequency (RF) Energy and Helium Gas	Radio frequency (RF) Energy and Helium Gas	Radio frequency (RF) Energy and Helium Gas
System Components	The Renuvion® Micro System consists of: ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator	The Apyx Plasma/RF System consists of: ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator	The Apyx Plasma/RF System consists of: ▪ RF Generator ▪ Disposable HP ▪ Foot pedal ▪ Power cord ▪ Gas regulator

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5. 510(k) Summary

Feature/ Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Renuvion® Micro Handpiece	**Renuvion® APR Handpiece (K223262)**	**Renuvion® APR Handpiece (K230272)**
	▪ Gas cylinder	▪ Gas cylinder	▪ Gas cylinder
Design & Energy Delivery Configuration	10cm shaft with front-port configuration 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	15cm and 27cm long shaft with a side port configuration (single or twin) and indicator lines on the shaft
Shaft and Tip Outer Diameter (OD)	Tip and Distal end of shaft OD: 2mm Shaft beyond distal end OD: 1.5mm	3mm	3mm

8. Substantial Equivalence Determination

The subject device design is based on the design of the Renuvion® APR Handpiece. The subject device has the same general intended use, principle of operation and system requirements. Both handpieces share many of the same technological characteristics except for the design modifications described in Section 3 above. The same performance testing completed for the Renuvion® APR Handpiece has also been conducted for the Micro Handpiece. The conclusions drawn from the bench and ex vivo tissue testing demonstrate that the Micro Handpiece is as safe and effective as the legally marketed primary predicate device and therefore is substantially equivalent.

9. Conclusion:

The Renuvion® Micro Handpiece is identical in principle of operation, mechanism of action, clinical use, general intended use, and system requirements to the predicate device, Renuvion APR (K223262 and K230272). Overall, the subject device is a smaller version of the predicate devices with minor design modifications to enable to the smaller device profile. The different technical characteristics do not raise new questions of safety or effectiveness of the subject device. The data presented in this 510(k) demonstrates that the subject device is as safe and effective as the predicate device and there have been no new questions of safety or effectiveness raised. Thus, supporting a substantial equivalence determination for the subject device.