



May 25, 2022

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

Re: K211652

Trade/Device Name: Renuvion Dermal Handpiece, Renuvion Dermal System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: May 24, 2022  
Received: May 25, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2023  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K211652

Device Name

Renuvion® Dermal Handpiece (APYX-044-DERM)

Indications for Use (Describe)

The Renuvion® Dermal System is an electrosurgical device for dermatological procedures for the treatment of moderate to severe wrinkles and rhytides, limited to patients with Fitzpatrick skin types I, II or III. The treatment is achieved through controlled heating of the outer layers of the skin so that part or all of the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis.

The Renuvion® Dermal Handpiece is only compatible with Apyx Medical Electrosurgical Generators.

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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**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:** Mrs. Priscilla Herpai, Global Regulatory Director  
Phone: (727) 803-8512  
Email: [priscilla.herpai@apyxmedical.com](mailto:priscilla.herpai@apyxmedical.com)

**Date Prepared:** May 27, 2021

**Trade Names (Model Numbers):** **Renuvion® Dermal Handpiece**  
(APYX-044-DERM)

**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  
NeoGen PSR System, Energist Ltd (K132754) -  
(formerly Portrait PSR System, Rhytec Inc.)

**2. Indications for Use**

The Renuvion® Dermal System is an electrosurgical system for dermatological procedures for the treatment of moderate to severe wrinkles and rhytides, limited to patients with Fitzpatrick Skin Types I, II or III. The treatment is achieved through controlled heating of the outer layers of the skin so that part or all of the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis. The Renuvion® Dermal Handpiece is only compatible with Apyx Medical Electrosurgical Generators.



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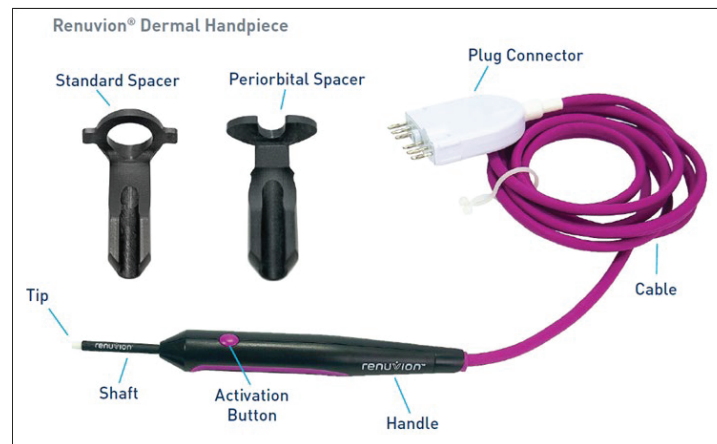
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### 3. Device Description

The Renuvion® Dermal Handpiece is a sterile single use electrosurgical (monopolar) device intended to be used in conjunction with a compatible Apyx Helium Plasma Generator (APYX-200P, APYX-RS3 – cleared under 510(k) K170188 & K192867) for the delivery of radiofrequency energy and/or helium plasma for the delivery of helium plasma for the non-invasive treatment of facial wrinkles and rhytides, in patients with Fitzpatrick skin types I, II or III. The Renuvion® Dermal Handpiece is pictured below.

The major components of the Renuvion® Dermal Handpiece are pictured in **Figure 1**.

**Figure 1.** Renuvion Dermal Handpiece



The Renuvion Dermal handpiece is part of the Renuvion System composed of the compatible Apyx generator, Foot switch, helium source, and patient grounding pad. The components of the system are pictured in **Figure 2**.

The handpiece is activated by pressing the activation button or by pressing the foot pedal on the footswitch accessory

The tip of the Renuvion® Dermal Handpiece is used to deliver thermal energy to tissue through a precise helium plasma beam. The device connects to the electrosurgical generator which is also connected to a helium gas tank and regulator. The device requires the use of a grounding pad plugged into the generator to complete the circuit. The device is offered only in one size, 44mm, catalog number APYX-044-DERM. The handpiece is activated by pressing the activation button on the handpiece or by pressing the purple foot pedal on the foot control accessory. The device is rated at 4.0kVpeak.

**Figure 2.** Renuvion Dermal System.



#### 4. Performance Data

Performance testing was conducted in accordance with *FDA's Guidance for Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* originally issued on August 15, 2016 and updated on March 9, 2020

##### a. **Bench Testing**

Performance testing was conducted to verify that the Renuvion® Dermal Handpiece and associated accessory (Renuvion® Dermal Spacer) met performance specifications. All acceptance criteria were met, and the device met all its performance and product requirements. The testing performed is summarized in the following table:

Test	Objective	Result
<b>Mechanical Verification &amp; Functionality</b>	Verify Mechanical functionality of the Renuvion® Dermal Handpiece and associated accessories, Renuvion® Dermal Spacers.	Mechanical functionality requirements met
<b>System Compatibility Testing</b>	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
<b>Thermal Tissue Effect</b>	Compare the tissue thermal effects of the subject device (Renuvion® Dermal Handpiece) with the reference device (Renuvion®/J-Plasma Precise Open Handpiece) using 4 different tissue types.	Thermal tissue effect requirements met



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Test	Objective	Result
<b>Inspectional Verification</b>	Document parameters that can be verified through inspection for the Renuvion® Dermal Handpiece.	Inspectional requirements met
<b>Packaging Validation</b>	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 was conducted on the system (subject device, Renuvion® Dermal Handpiece (HP), and the compatible Electrosurgical Generator, APYX-200P and APYX-RS3) to ensure compliance with the following recognized standards and all results were passing:

ANSI/AAMI/IEC ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance

ANSI/AAMI/IEC 60601-2-2:2017 Medical electrical equipment - Part 2-2: Requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and Tests.

ANSI/AAMI/IEC 62366:2015 Medical devices - Part 1: Application of usability engineering to medical devices

**c. Biocompatibility Testing**

The biocompatibility evaluation for the Renuvion® Dermal 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 and AAMI/ANSI/ISO 10993-1:2009 standards, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process”. The Renuvion® Dermal Handpiece (subject device) is considered a surface contacting device with contact to breached or compromised surfaces. Therefore, the following tests were conducted and passed in accordance with the respective ISO 10993 series recognized consensus standard:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Material Mediated Pyrogen/Pyrogenicity





## 5. Pre-Clinical & Animal Studies

Two pre-clinical animal studies were conducted to establish the equivalence between the subject device and the predicate device, NeoGen® PSR System by Energist (formerly the Portrait PSR System by Rhytec). These pre-clinical studies were designed to provide a measurement (using histology under magnification) of the depth of the thermal damage zone (i.e., coagulation necrosis) on live porcine skin tissue at their minimum and maximum recommended power settings for dermatological wrinkle reduction procedures for moderate to severe wrinkles and rhytides.

These two (2) pre-clinical studies demonstrated that the depth of thermal effect for the Renuvion® Dermal System (subject Device) was less than or comparable to the depth of thermal effect for the predicate NeoGen PSR system in a porcine model. The results of these pre-clinical studies support the safety and substantial equivalence of the Renuvion® Dermal System for dermatological wrinkle reduction procedures in comparison to the predicate nitrogen plasma technology (NeoGen PSR System, K132754).

## 6. Human Clinical Trials

The clinical performance of the subject device (**Renuvion® Dermal Handpiece**) is supported by the results of a Clinical IDE study performed (G170151) using the subject device. This clinical study was a prospective, multicenter, single arm clinical study evaluating the use of the Renuvion® Dermal System for dermatological wrinkle reduction conducted at 3 investigational centers in the United States as an evaluator-blinded prospective study of 55 study subjects who were seeking a procedure for the purpose of improving facial appearance by reducing facial wrinkles and rhytides. Each study subject received one single-pass full-face treatment with the **Renuvion® Dermal System**.

**Primary Effectiveness Endpoint:** The primary effectiveness endpoint was the proportion of subjects with at least one-point improvement from Baseline in Fitzpatrick Wrinkle and Elastosis Scale (FWS) at 90-days post-procedure as determined by 2 out of 3 blinded Independent Photographic Reviewers (IPR) assessment of photographs.

**Primary Safety Endpoint:** The primary safety endpoint was the evaluation of adverse events up to the 3-month visit following the procedure.

### a. **Effectiveness Results**

Of 55 subjects treated, 92.7% (51/55) were scored to have at least a one-point improvement, 25.5% were scored to have at least a two- point improvement, and 5.5% were scored to have at least a three-point improvement on the Fitzpatrick Wrinkle and Elastosis Scale (FWS) at 90 days as determined by Independent Photographic Reviewers (IPRs).





### b. Safety Results

The study reported no serious adverse events (SAEs) related to the study device or procedure, and adverse events (AEs) were in line with the expectations of dermatological wrinkle reduction procedures involving the application of controlled heat to the epidermis to selectively render it non-viable with subsequent thermal modification of the underlying dermis to prompt a healing response. The most common events reported were, edema, erythema, and post-inflammatory hyperpigmentation.

The rate of AEs for the subject device is consistent with the expected range that has been observed for the predicate device, as reported in the literature. Based on the clinical performance as documented in the clinical study (G170151), the Renuvion® Dermal System was found to have a safety and effectiveness profile that is consistent with other legally marketed dermatological wrinkle reduction technologies such as the predicate device.

Table 2 is a direct comparison of adverse events for the Renuvion Dermal Handpiece (subject device) compared to the Rhytec/Energist (predicate device) established in literature.

**Table 2.** Adverse Event Profile Comparison for Subject and Predicate Device

Adverse Event	Renuvion Dermal System (n=55)	Rhytec/Energist Predicate (n=24)
Crusting	1.8%	100% <sup>1</sup>
Edema	34.5%	100% <sup>1</sup>
Erythema	16.4%	100% <sup>1</sup>
Milia/Acne	12.7%	Not Reported
Pruritus/Itching	9.1%	Not Reported
Hypertrophic Scar	3.6%	4.2% <sup>1</sup>
Post-inflammatory Hyperpigmentation	14.5%	"A number of patients" at D90 <sup>1</sup>
Telangiectasia	0%	Not Reported



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Discoloration/Hypopigmentation	0%	0% <sup>1</sup>
Delayed Healing	7.3%	Not Reported
Pain D0 Post-Op VAS Score (0=lowest, 10=highest)	4.3	4.3 <sup>1</sup>
Lid Retraction	0%	Not Reported

<sup>1</sup>: Kilmer S, Semchyshyn N, Shah G, Fitzpatrick R. A pilot study on the use of a plasma skin regeneration device (Portrait PSR3) in full facial rejuvenation procedures. *Lasers Med Sci.* 2007 Jun;22(2):101-9 doi: 10.1007/s10103-006-0431-9. Epub 2007 Mar 7. PMID: 17342383.

### c. Human Clinical Trial Outcome Summary

The clinical study demonstrated both safety and effectiveness, as endpoints related to effectiveness were met and there were no serious adverse events reported related to the study device or procedure. The risks and AE profile are comparable between the subject device and what is reported in published literature for the predicate device as long as the recommended treatment parameters are followed. The effectiveness outcomes are as good or better for the subject device as compared to the predicate device.

- ❖ The totality of the data shows benefit to all subjects via the reduction of facial wrinkles and rhytides in subjects with Fitzpatrick Skin Type I, II, and III. The primary effectiveness endpoint for this study was achieved at 92.7%.
- ❖ The primary safety endpoint identified the type and frequency of adverse events, and no new or different risks or adverse events were identified. There were no serious adverse events reported as related to the study device or the study procedure. The adverse events were comparable to those reported for the predicate device and fully ablative dermatological wrinkle reduction procedures in general using other FDA-cleared energy-based modalities as long as the recommended treatment parameters are followed.
- ❖ These data support the proposed Indications for Use of the product and substantial equivalence to the predicate device (Energist NeoGen Nitrogen Plasma K132754) for a 510(k) submission.

Based on the totality of data (safety variables and success criteria), there is sufficient assurance that safety and effectiveness has been demonstrated and clinically meaningful benefits have been observed in a majority of subjects. The safety and effectiveness conclusions drawn from the clinical studies demonstrate that there is statistically significant data to support the safety, effectiveness, and performance of the **Renuvion® Dermal System** for the treatment of moderate to severe facial wrinkles and rhytides in patients with Fitzpatrick Skin Types I, II or III and the benefits of Renuvion outweigh the risks. The subject device clinical study results, when compared to the predicate device safety and effectiveness data as stated in literature also supports substantial equivalence of the Renuvion Dermal Handpiece.



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**7. Substantial Equivalence**

The predicate device was selected because the subject device's intended use is a subset of the intended use for the primary predicate device (*electrosurgical device for dermatologic treatment of wrinkles and rhytides - the treatment is achieved through controlled heating of the outer layers of the skin so that part or all the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis*). The reference device was selected due to having the same principle of operation, mechanism of action, sterilization methods and technology used for device performance as the subject device, other than the few design modifications described in the submission. A summary of the subject device and predicate device comparison is provided below.

Feature/ Characteristic	Subject Device	Predicate Device
	Renuvion® Dermal Handpiece	NeoGen PSR System, K132754
<b>Indications for Use</b>	The Renuvion® Dermal system is an electrosurgical device for dermatological procedures for the treatment of moderate to severe wrinkles and rhytides, limited to patients with Fitzpatrick skin types I, II or III. The treatment is achieved through controlled heating of the outer layers of the skin so that part or all the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis. The Renuvion® Dermal Handpiece is only compatible with Apyx Medical Electrosurgical Generators	The NeoGen PSR system is an electrosurgical device for the treatment of dermatologic conditions including acne scars, actinic keratosis, superficial skin lesions and the treatment of wrinkles and rhytides. The treatment is achieved through controlled heating of the outer layers of the skin so that part or all the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis.
<b>Software</b>	Renuvion® Dermal handpiece does not contain software; Renuvion generator contains firmware	NeoGen PSR handpiece does not contain software; NeoGen generator contains software
<b>Sterility</b>	Single Use disposable Sterile (EO) Handpiece	Handpiece clean but non-sterile
<b>Use Environment</b>	Doctor's Office, Surgery Center, or similar environment	Doctor's Office/ Clinics or hospitals
<b>Clinical Application</b>	Dermatologic on intact & broken skin; Dermal procedures (facial)	Dermatologic on intact & broken skin; Dermal procedures (facial & non-facial)
<b>Prescription or OTC</b>	Prescription Use Only	Prescription Use Only
<b>Energy Source</b>	Electrosurgical generator	Electrosurgical generator
<b>Energy Type</b>	Inert Gas Plasma (helium)	Inert Gas Plasma (nitrogen)
<b>Waveform</b>	Radiofrequency waveform	Radiofrequency waveform



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Feature/ Characteristic	Subject Device	Predicate Device
	Renuvion® Dermal Handpiece	NeoGen PSR System, K132754
<b>Device Activation</b>	Foot Pedal Activation or button hand activation	Foot Pedal Activation
<b>User Interface</b>	Generator buttons and displays	Generator buttons and displays
<b>Limitations on device use</b>	Device to be used by trained medical staff only, in a Doctor's Office, Surgery Center or similar environment	Device to be used by trained medical staff only, in a Doctor's Office, Surgery Center or similar environment
<b>Mode of Action</b>	The treatment is achieved through controlled heating of the outer layers of the skin so that part or all the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis	The treatment is achieved through controlled heating of the outer layers of the skin so that part or all of the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis
<b>Power delivered to patient</b>	3.2 – 8.55 W	1 – 10 W
<b>Procedures &amp; Anatomical site</b>	Dermatological procedures	Dermatological procedures
<b>Plasma Settings</b>	Controls on the generator allows the user to vary the power delivered to the patient	Controls on the generator allows the user to vary the power delivered to the patient
<b>Compatibility</b>	Compatible only with specific generator	Compatible only with specific generator
<b>Connector</b>	Compatible only with specific generator	Compatible only with specific generator

## 8. Conclusion

Clinical testing of the Renuvion® Dermal System (subject device) demonstrated that the device performed as intended with a favorable safety profile. The primary effectiveness endpoint FWS improvement score, investigator FWS score, and patient assessment of results yielded comparable or more improved outcomes than the predicate device. The safety profile of the subject device is comparable to the predicate device; no new or different risks were identified, and adverse event rates were comparable to the predicate device rates when used following recommended treatment settings. The Renuvion® Dermal Handpiece safety and performance has been further confirmed by the results of the performance bench and animal testing. Technologically, there are no differences between the subject and predicate device that would raise new or different questions regarding safety or effectiveness; the maximum depths of thermal effect measured for the Renuvion® Dermal Handpiece are less than or statistically equivalent to the predicate device as measured by histopathology. In conclusion,

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the totality of the data (clinical, pre-clinical animal data, performance bench testing, and benefit-risk assessment) demonstrate that the Renuvion® Dermal Handpiece is substantially equivalent to the predicate device (NeoGen PSR System, Energist Ltd.- K132754) for the requested indication for use.