October 11, 2022

Apyx Medical Corporation
David Ceretti
5115 Ulmerton Road
Clearwater, Florida 33760-4004

Re: K221830
Trade/Device Name: Apyx One Console
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 9, 2022
Received: September 12, 2022

Dear David Ceretti:

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)*

K221830

Device Name

Apyx One Console (APYX-ONE)

Indications for Use *(Describe)*

The Apyx One Console is indicated for delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/J-Plasma handpieces.

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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510K Summary

1. General Information

Submitted by:
Apyx Medical Corporation
5115 Ulmerton Road
Clearwater, FL 33760-4004

Establishment Registration #: 3007593903

Submitter FAX Number: (727) 322-4465

Contact Person:
David Ceretti, Pre-Market Regulatory Affairs Manager
5115 Ulmerton Road
Clearwater, FL 33760-4004
Phone: (727) 803-8508
Email: David.Ceretti@Apyxmedical.com

Date Prepared: June 21, 2022

Trade Names (Model Number):
Apyx One Console
(APYX-ONE)

Common Name: Electrosurgical Generator

Classification:
Class II per 21 CFR 878.4400 - Electrosurgical Cutting and Coagulation Device and Accessories
Product Code: GEI

Predicate Device(s):
Predicate Device
Apyx Helium Plasma Generator
(K192867)

2. Indications for Use

The Apyx One Console is indicated for the delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/J-Plasma handpieces.

3. Device Description

The Apyx One Console is an electrosurgical generator that delivers radiofrequency (RF) energy to cut and coagulate soft tissue. It can also deliver Helium plasma energy for cutting, coagulation, and ablation of soft tissue. Like the predicate, the Apyx One Console provides standard electrosurgical energy and Helium Plasma energy, with no changes to the intended use, electrosurgical modes, output power waveforms, or

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maximum power settings. The Apyx One Console is a modified version of the primary predicate device that was cleared under K192867 (Apyx Helium Plasma Generator), with a no change to the intended use.

The Apyx One Console has a Graphical User Interface (GUI), Remote Services will be available using an attached cellular module to assist in troubleshooting the generator in the field, a helium Gas Pressure Transmitter, and two monopolar ports.

The Remote Service module will also provide non-HIPPA data to a cloud data system which will log the various settings of the generator throughout its use.

4. Performance Data

a. Electrical safety and electromagnetic compatibility (EMC) testing were conducted, and the results demonstrated that the Apyx Helium Plasma Generator performance is in accordance with the following standards:

International Standard	Description
ANSI/AAMI/IEC ES60601-1:2005/(R2012)+A1:2012	*Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*
AAMI/ANSI/IEC 60601-1-2:2014 (4th Edition)	*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
AAMI/ANSI/IEC-60601-2-2:2017 (6th Edition)	*Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
IEC 62366-1:2015+AMD1:2020	*Medical devices – Application of usability engineering to medical devices IEC 62366:2007*

b. Performance testing was completed to demonstrate substantial equivalence of the subject device to the predicate device (K192867) and in accordance with the FDA Guidance Documents:

Test	Objective	Results
Electrical Safety	To verify electrical product and performance specification requirements.	The electrical functionality of the generator was verified to meet performance specification requirements.

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Software / FirmwareVerification & Validation	To validate the field programmable gate array (FPGA) procedure and the logic design used in the generator.	The results demonstrated that the system and FPGA perform as intended and according to the product specifications.
Mechanical Verification	To verify mechanical product and performance specification requirements.	The results verified that the mechanical design meets the product and performance requirements.

Results of the bench and software/Firmware testing demonstrate that the Apyx One Console is equivalent to the predicate device in terms of safety and effectiveness.

5. Substantial Equivalence

Feature/ Characteristic	Subject Device	Predicate Device
	Apyx One Console	**Apyx Helium Plasma Generator (K192867)**
Intended Use / Indications for Use	The Apyx One Console is indicated for the delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/ J-Plasma handpieces.	The Apyx Helium Plasma Generators (owned by Apyx Medical) are indicated for delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/ J-Plasma handpieces.
Technology / Energy Used, Delivered	Uses High Frequency Radiofrequency (RF) energy to create clinical effect. The electrical properties of the waveform (frequency, peak, and duration) produce the clinical effect (i.e. coagulation and cutting). For soft tissue coagulation using Helium gas, the flow rate produces clinical effect (i.e. coagulation and ablation).	Uses High Frequency Radiofrequency (RF) energy to create clinical effect. The electrical properties of the waveform (frequency, peak, and duration) produce the clinical effect (i.e. coagulation and cutting). For soft tissue coagulation using Helium gas, the flow rate produces clinical effect (i.e. coagulation and ablation).
User Interface	Touch Screen display and LEDs	Push buttons, Seven segment display and LEDs.

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Available Modes	Cut (2), Blend (3), Coagulation (3: pinpoint, spray, gentle), Bipolar (3: Macro, Micro, Standard) with auto bipolar option, and J-Plasma (2 -with Active accessory and with Passive accessory)	Cut (2), Blend (3), Coagulation (3: pinpoint, spray, gentle), Bipolar (3: Macro, Micro, Standard) with auto bipolar option, and J-Plasma (2 -with Active accessory and with Passive accessory)
Electrical Safety Standards/	Complies with ANSI/AAMI ES60601-1:2005 (R2012), IEC60601-1-2 (electromagnetic compatibility), and IEC60601-2-2:2017 standard for the safety of electrosurgical equipment.	Complies with ES60601-1 (third edition), IEC60601-1-2 (electromagnetic compatibility), and IEC60601-2-2 (fourth edition) standard for the safety of electrosurgical equipment.

6. Conclusion

The Apyx One Console is a modification to the predicate device that was cleared in K192867 (Apyx Helium Plasma Generator) There are no changes to the intended use, principle of operation, or mechanism of action. Like the predicate, the subject device is intended for the delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during laparoscopic surgical procedures.

Technological differences between the Apyx One Console and the predicate do not raise any new concerns of safety or effectiveness and the performance testing demonstrated that the device performs as intended.

Based upon the intended use, comparison of technical characteristics and performance testing provided in this pre-market notification, the Apyx One is substantially equivalent to the predicate device and does not raise new or different questions of safety and effectiveness.