May 8, 2026

Apyx Medical Corporation
Nikita Gajbhiye
Pre-Market Regulatory Affairs Manager
5115 Ulmerton Road
Clearwater, Florida 33760

Re: K253396
Trade/Device Name: AYON™ Power Liposuction Sub-System (AYON™ SYSTEM)
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: QPB
Dated: December 19, 2025
Received: December 22, 2025

Dear Nikita Gajbhiye:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Alicia Hemphill -S

Digitally signed by Alicia Hemphill -S
Date: 2026.05.08 12:22:51 -05'00'

Alicia L. Hemphill (Johnson), MS
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
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Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253396

Please provide the device trade name(s).

AYON™ Power Liposuction Sub-System (AYON™ SYSTEM)

Please provide your Indications for Use below.

The AYON™ Power Liposuction Sub-System is used for aesthetic body contouring.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

1. General Information

Submitted by: Apyx Medical Corporation
5115 Ulmerton Road
Clearwater, Florida 33760-4004
United States of America

Contact Person: Nikita Gajbhiye

Regulatory Affairs Manager
(Pre-Market)
Phone: 857-210-6492
Email: nikita.gajbhiye@apyxmedical.com

Date Prepared: December 18th, 2025

Trade Name: **AYON™ Power Liposuction Sub-System**
(AYON™ SYSTEM)

Common Name: Liposuction System

Classification: Class II per 21CFR 878.5040 - Suction Lipoplasty System

Product Code QPB

Predicate Device: PAL System (K212024) by MicroAire Surgical Instruments, LLC

2. Proposed Indications for Use

The AYON™ Power Liposuction Sub-System is used for aesthetic body contouring.

3. Device Description

The AYON Body Contouring System™ includes an Ultrasound Sub-system, Power Liposuction Sub-system, an Infiltration Sub-system, and an Aspiration Sub-system. The subject device for this submission is the AYON Body Contouring System™ addition of the Power Liposuction Sub-System. The Ultrasound, Aspiration, and Infiltration Sub-Systems are identical to the Predicate Device, the AYON Body Contouring System™ without the Power Liposuction Sub-System, cleared under K244050; there have been no changes made to these three sub-systems. The Power Liposuction Sub-system includes Power Liposuction Handpieces, Power Liposuction cables Infiltration and Aspiration Tubing Adaptors. The Power Liposuction Handpiece can be used with commercially available cannulas. There are two connecting ports available on the AYON CONSOLE for this feature, and both may be used at the same

time. The Power Liposuction handpieces have two buttons located on the handpieces. These can control the activation of the handpieces as well as either the aspiration or infiltration pump.

The AYON Body Contouring System™ may also accommodate other equipment, including commercially available electrosurgical generators owned by Apyx® Medical, such as the APYX-ONE Console. The controls for the Power Liposuction are integrated into a touch screen utilizing a graphical user interface on the AYON™ Console.

4. Performance Data

The relevant FDA guidance documents were followed for all aspects of performance testing.

a. Mechanical and Physical Bench Testing

The Power Liposuction Sub-system was tested separately and as a combined system to demonstrate system compatibility of the subsystems and devices/accessories. The subsystem testing included;

- Power Liposuction Handpiece Reciprocation Performance and Dimensional Analysis, Pull Force and Fatigue testing
- Tubing Adaptor Mechanical Performance and conformity assessment to ISO 10079-1 and 10079-4.

b. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety testing was performed in accordance with IEC 60601-1-1. Electromagnetic Compatibility testing was performed in accordance with IEC 60601-1-2 and 60601-4-2. Wireless emissions testing was conducted for the wireless footswitch.

c. Software and Cybersecurity

Software and Cybersecurity Verification and Validation testing were performed in accordance with ISO 62304.

d. Biocompatibility Testing

Biological evaluation per ISO 10993-1 was conducted on the patient contacting materials.

e. Reprocessing

The reprocessing of sterile products was tested in accordance with ISO 17665.

f. Sterility

The processing of sterile products was tested in accordance with ISO 11135.

g. Packaging

The product packaging was tested in accordance with ISO 11607.

5. Clinical Performance

No clinical studies were required to support the substantial equivalence of the device. The non-clinical testing detailed in this submission support the substantial equivalence of the device.

6. Substantial Equivalence

The subject device for this submission is the AYON Body Contouring System™ addition of the Power Liposuction Sub-System. The identified Primary Predicate Device is the PAL System, manufactured by MicroAire Surgical Instruments, LLC under K212024.

Table 1. Substantial Equivalence Table

	AYON™ Power Liposuction Sub-System Subject Device K253396	**MicroAire PAL System Primary Predicate Device K212024**	**Device Comparison**
Intended Use	Power Assisted Liposuction: For aesthetic body contouring.	Power Assisted Liposuction: For aesthetic body contouring.	Identical
Product Code/ Regulation Number	QPB, 21 CFR 878.5040	QPB, 21 CFR 878.5040	Identical
User	Used by trained Physicians in an operating environment.	Only trained and experienced healthcare providers/professionals should use this medical equipment.	Same
Power	AC Powered Voltage: 120 VAC Frequency: 50-60 Hz	AC Powered Voltage: 100-240 VAC Frequency: 50/60 Hz	Similar, accommodates United States voltage.
Mechanism of Action	Power Liposuction: AYON Power Liposuction Sub-System™ is an electronic control system designed to reciprocate a cannula in lipoplasty applications.	Power Assisted Liposuction: MicroAire power assisted liposuction is an electronic control system designed to reciprocate a cannula in lipoplasty applications.	Identical
User Interface/Controls	Single touchscreen utilizing a graphical user interface, on/off switches	The color touchscreen display provides an intuitive graphical user interface that allows users to view system status and	Identical

	AYON™ Power Liposuction Sub-System Subject Device K253396	**MicroAire PAL System Primary Predicate Device K212024**	**Device Comparison**
		set parameters with a touch of the screen.	
Operating Mode	Use the sliding bar on the Console display to set the speed of reciprocation of the Power Liposuction Handpiece (up to 100%)	Use the thumb-throttle on the PAL Handpiece to adjust the speed of reciprocation during the procedure; use the sliding bar on the Console display to set the maximum speed (up to 100%)	Similar, both control mechanisms provide the ability to adjust the handpiece speed.
Power Liposuction Handpiece			
Speed Control	Touch Screen and Handpiece	Touch Screen and Handpiece	Identical
Number of Attachable Devices	Two (2) Handpieces	Two (2) Handpieces	Identical
Electrical Safety Testing Passed	Meets applicable IEC requirements: IEC/EN 60601-1-2 IEC 60601-1	Meets applicable IEC requirements: IEC/EN 60601-1-2 IEC 60601-1	Identical
Performance	4000 ± 10% strokes/ minute	4000 – 5000 strokes/min.	Similar, the device operates within the range when set to high-speed. The subject device has a slightly tighter specification (3600 - 4400 strokes per minute).
Stroke Distance	2.8 mm (±0.4 mm)	2.8 mm (±0.4 mm)	Identical
Power Source	Console, detachable cable	Console, detachable cable	Identical
Duty Cycle	Duty cycle of 2 hours continuous use/2 hours off.	Duty cycle of 2 hours continuous use/2 hours off.	Identical
Sterilization	Re-usable items are autoclavable by end user, steam sterilization	Re-usable items are autoclavable by end user, steam sterilization	Identical
Tubing Adaptor accessory			

	AYON™ Power Liposuction Sub-System Subject Device K253396	**MicroAire PAL System Primary Predicate Device K212024**	**Device Comparison**
Tubing Compatibility	Tubing Adaptor provides compatibility with standard, commercially available infiltration and aspiration tubing	Compatible with Aspiration Tubing and Infiltration Tubing	Same

7. Substantial Equivalence Determination

The subject and primary predicate device have the same intended use and comply with the relevant standards and FDA guidance documents with regard to electrical safety, electromagnetic compatibility, software and cybersecurity, biocompatibility, transportation, packaging, sterilization.

The data provided shows the Power Liposuction Sub-system and associated handpiece reciprocates with the same performance (speed, distance) compared to the primary predicate device. The AYON Body Contouring System™ continues to operate as intended, following the addition of the fourth sub-system, the Power Liposuction Sub-system.

8. Conclusion

The performance data presented in this submission supports substantially equivalent performance between the subject device and the primary predicate device, MicroAire PAL System cleared under K212024.