August 21, 2026

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

Re: K261710
Trade/Device Name: AYON™ Power Liposuction Cannulas and AYON™ Power Liposuction Cannula Adaptors
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: QPB
Dated: May 22, 2026
Received: May 22, 2026

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: 2026.08.21 09:27:12 -05'00'

Alicia L. Hemphill (Johnson), MS
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and 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.	K261710

Please provide the device trade name(s).

AYON™ Power Liposuction Cannulas and AYON™ Power Liposuction Cannula Adaptors

Please provide your Indications for Use below.

The AYON™ Power Liposuction Cannulas are indicated for removal of tissue or fluid from the body during general surgical procedures, including suction lipoplasty, for the purpose of aesthetic body contouring.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510k 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) Email: Nikita.Gajbhiye@ApyxMedical.com Phone: +1 (857) 210-6492
Date Prepared	May 21, 2026
Trade Name	AYON™ Power Liposuction Cannulas and AYON™ Power Liposuction Cannula Adaptors
Common Name	Cannula and Cannula Adaptor
Classification	Class II per 21CFR 878.5040 - Suction Lipoplasty System
Product Code	QPB
Predicate Device	MicroAire® PAL Multi-Use Cannulas by MicroAire® Surgical Instruments, Inc. (K171286) Class II per 21CFR 878.5040 - Suction Lipoplasty System Product Code: QPB
Reference Device	Aspiration and Infiltration Cannulas manufactured by Black & Black Surgical Inc. (K113795) Class II per 21CFR 878.5040 - Suction Lipoplasty System Product Code: QPB

2. Indications for Use

The AYON™ Power Liposuction Cannulas are indicated for removal of tissue or fluid from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring.

3. Device Description

The AYON™ Body Contouring System previously cleared under K244050 includes an Ultrasound Sub-System, an Infiltration Sub-System, and an Aspiration Sub-System. A traditional 510(k) to add a Power Liposuction Sub-System to the AYON™ Body Contouring System was cleared under K253396.

The purpose of this additional Traditional 510(k) is to include the following devices/accessories within the Power Liposuction Sub-system only.

- AYON™ Power Liposuction Cannulas that can connect directly to the Apyx Power Liposuction Handpiece.
  - AYON™ Power Liposuction Spatula Cannula; 3mm x 15cm
  - AYON™ Power Liposuction Ghost Cannula; 3mm x 30cm
  - AYON™ Power Liposuction Mercedes Cannula; 3mm x 30cm
  - AYON™ Power Liposuction Mercedes Cannula; 4mm x 35cm
  - AYON™ Power Liposuction Mercedes Cannula; 4mm x 40cm
  - AYON™ Power Liposuction Mercedes Cannula; 4mm x 30cm, curved
  - AYON™ Power Liposuction Basket Cannula; 4mm x 30cm, bent
  - AYON™ Power Liposuction Basket Cannula; 4mm x 30cm, straight
  - AYON™ Power Liposuction Basket Cannula; 5mm x 30cm, straight
- AYON™ Power Liposuction Cannula Adaptors that can connect commercially available infiltration and aspiration cannulas to the Power Liposuction Handpiece.
  - AYON™ Power Liposuction Cannula Adaptor – Luer Lock
  - AYON™ Power Liposuction Cannula Adaptor – Threaded
  - AYON™ Power Liposuction Cannula Adaptor – Moeller

The AYON™ Power Liposuction Cannulas can be connected directly to the AYON™ Power Liposuction handpiece which is used for aesthetic body contouring. The Power Liposuction Handpiece reciprocates the attached cannula in a rapid back-and-forth movement, which enhances the user's ability to dislodge fat with less manual effort. Additionally, based on user preference, Cannula Adaptors can be used which allow connection of commercially available infiltration and aspiration cannulas to the Power Liposuction Handpiece.

There are no changes to the previously cleared Ultrasound Sub-System, Infiltration Sub-System, Aspiration Sub-System, or the Power Liposuction Sub-System as the result of the changes proposed in this 510k.

4. Comparison Of Technological Characteristics with the Predicate Device

The AYON™ Power Liposuction Cannulas are available in diameter, length, and distal tip fenestration configurations that fall within the ranges established by the predicate devices. The cannulas are manufactured from the same stainless-steel materials and utilize the same intended use, operating principles, and fundamental technology as the predicates (see **Table 1** below for comparison with the predicates). Performance testing demonstrated that the cannulas perform as intended and do not raise additional concerns of safety and effectiveness. Thus, concluding there are no technological differences between the subject and the predicate devices.

5. Performance Data (Bench)

In order to demonstrate the substantial equivalence of the proposed device to the identified predicate device, Apyx Medical Corporation completed the following non-clinical performance testing. The resulting test data showed that the subject devices meet all the design and biocompatibility requirements, confirming that the design outputs meet the design inputs and device specifications, thus demonstrating substantial equivalence of the proposed devices/accessories to the predicate.

The AYON™ Power Liposuction Cannulas and the AYON™ Power Liposuction Cannula Adaptors, when tested with commercially available infiltration and aspiration cannulas, passed the following performance testing per internal testing protocols developed in accordance with applicable standards:

- Biocompatibility testing per ISO 10993-1
- Reciprocation Performance
- Compatibility testing with the AYON™ Power Liposuction Handpiece
- Mechanical strength (fatigue, tensile/pullout force, compression, bend, torsion strength)
- Suction Equipment testing (ISO 10079-1: 2022 and ISO 10079-4: 2021)
- Cleaning 2015/(R)2017 FDA guideline, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- Sterilization per ISO 17665:2024 series, Sterilization of Health Care Products – Moist Heat – Requirements for Development, Validation and Routine Control of a Sterilization

Process for Medical Devices and 2015/(R)2017 FDA guideline, reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

- Shelf-life testing: N/A, devices are provided non-sterile

6. Clinical Performance

There was no human clinical testing required to support the medical device, as the indications for use are equivalent to the predicate device. The non-clinical testing detailed in this 510(k) submission supports the substantial equivalence of the devices/accessories.

7. Substantial Equivalence

The subject devices / accessories are substantially equivalent to the primary device in terms of intended use, regulatory classification, and fundamental technological characteristics.

Table 1 below provides a detailed summary of the substantial equivalence between the subject device and the predicates.

Table 1: Substantial Equivalence Summary

	Subject Device / Accessory	**Primary Predicate**	**Reference Device**	
Substantial Equivalence Characteristics	**AYON™ Power Liposuction Cannula and AYON™ Cannula Adaptors**	**MicroAire® PAL Multi-Use Cannulas and PAL-730 Manual Wand[1]**	**Black & Black Surgical Inc., Aspiration and Infiltration Cannulas**	**Device Comparison**
510 (k) Information				
Trade Name	AYON™ Power Liposuction Cannulas and AYON™ Cannula Adaptors	MicroAire® PAL Multi-Use Cannula	Black & Black Surgical Inc., Aspiration and Infiltration Cannulas	Not applicable
Medical Specialty	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	Same
Product Code	QPB	QPB	QPB	Same
Regulation Number	21 CFR 878.5040 Suction lipoplasty system	21 CFR 878.5040 Suction lipoplasty system	21 CFR 878.5040 Suction lipoplasty system	Same
510k Number	K261710 (This submission)	K171286	K113795	Not applicable
Classification	Class II	Class II	Class II	Same
Indications for Use	Indicated for removal of tissue or fluid from the body during general surgical procedures, including suction lipoplasty, for the purpose of aesthetic body contouring.	Indicated for the removal of tissue or fluid from the body during general surgical procedures, including suction Lipoplasty, for the purpose of aesthetic body contouring	The aspiration and infusion cannulas and needles are indicated for aesthetic body contouring and general tissue aspiration	Similar
Device Overview				
User	Used by trained Physicians in an operating environment.	Used by trained Physicians in an operating environment.	Used by trained Physicians in an operating environment.	Same
Mechanism of Action	The AYON™ Power Liposuction Cannulas attach to the Power Liposuction Handpiece and tubing	The cannulas attach to the PAL-730 Manual Wand and suction tubing via a cannula hub. This	The cannulas and needles remove fluid, soft tissue and exudates and infuse by	Same

[1] Only the MicroAire® PAL Multi-Use Cannula from K171286 was used for demonstrating substantial equivalence as it relates to the AYON™ Power Liposuction Cannulas.

	Subject Device / Accessory	Primary Predicate	Reference Device	
Substantial Equivalence Characteristics	**AYON™ Power Liposuction Cannula and AYON™ Cannula Adaptors**	**MicroAire® PAL Multi-Use Cannulas and PAL-730 Manual Wand[1]**	**Black & Black Surgical Inc., Aspiration and Infiltration Cannulas**	**Device Comparison**
	via a cannula hub. These cannulas connect to the Power Liposuction Handpiece to remove fluid or tissue from the body using tubing connected to the cannula hub and the AYON™ Body Contouring Infiltration and Aspiration Sub-Systems, respectively.	tubing connects to an external suction source (not part of the PAL System). Fluid and tissue is removed from the body via the tubing assisted by the external suction source.	using a hollow stainless-steel tube, multiple tips, a handle and attachment connectors that are used in reusable and disposable configurations.	
Performance Characteristics	Designed to be used with AYON™ Power Liposuction Handpiece	Designed to be used with the PAL-730 Manual Wand	Designed to be used with a manual liposuction handpiece with either a Luer Lock Hub or a Syringe Hub	Similar
Configurations	Diameters: 3 mm, 4 mm and 5 mm Lengths:15 cm, 30 cm, 35 cm and 40 cm	Diameters: 2.4 mm, 3.0 mm, 4.0 mm 5.0 mm Lengths: 15cm, 22 cm, 30 cm and 40 cm	Diameters: 2 mm, 3 mm, 4 mm, 5 mm and 6 mm Lengths: 15 cm, 20 cm, 26 cm, 32 cm and 36 cm	Similar – Subject device configurations fall within the range of offering for the predicate device
Available Fenestration Types (Distal end)	Spatula Ghost Mercedes Basket	Mercedes Basket Double Mercedes Offset Double Mercedes Tri-Port II Mirrored Tri-Port II Tri-Port III Helixed Tri-Port III Multi-Hole Del Vecchio Track-12	Mercedes Basket Spatula Accelerator	Similar – Subject device fenestration types fall within the range of offering for the predicate device. Note: The subject Ghost configuration is similar to Primary Predicate Tri-Port II version.

	Subject Device / Accessory	**Primary Predicate**	**Reference Device**	
Substantial Equivalence Characteristics	**AYON™ Power Liposuction Cannula and AYON™ Cannula Adaptors**	**MicroAire® PAL Multi-Use Cannulas and PAL-730 Manual Wand[1]**	**Black & Black Surgical Inc., Aspiration and Infiltration Cannulas**	**Device Comparison**
Material	Cannula (device): Stainless-steel 304 and 17-7	Stainless-steel 304	Cannula: Stainless steel 17-7	Same
Sterility	Supplied nonsterile; Steam sterilized by end user	Supplied nonsterile; Steam Sterilized by end user	Supplied nonsterile; Steam Sterilized by end user	Same
Single-Use	No	No	No	Same
Shelf-life	Not applicable (device is provided non-sterile) The device is considered shelf stable.	Not applicable (device is provided non-sterile) The device is considered shelf stable.	Not applicable (device is provided non-sterile) The device is considered shelf stable.	Same
Biocompatibility	In compliance with ISO 10993-1	In compliance with ISO 10993-1	In compliance with ISO 10993-1	Same

8. Substantial Equivalence Determination

The subject devices and primary predicate devices have equivalent indications for use and comply with the relevant standards and FDA guidance documents with regard to performance bench testing, biocompatibility, cleaning and reprocessing.

The performance testing data supports the substantial equivalence of the device.

9. Conclusion

The performance data presented in this submission supports substantially equivalent performance between the subject devices/accessories, and the predicate devices, The devices have the same indications for the removal of tissue or fluid from the body during general surgical procedures (primary predicate), including suction lipoplasty, for the purpose of aesthetic body contouring.