May 12, 2025

Apyx Medical Corporation
Angela Huber
Global Director of Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760

Re: K244050
Trade/Device Name: AYON Body Contouring System (AYON SYSTEM)
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: QPB
Dated: December 31, 2024
Received: April 11, 2025

Dear Angela Huber:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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: 2025.05.12 15:21:00 -05'00'

Alicia L. Hemphill (Johnson), M.S.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K244050

Device Name
AYON(TM) Body Contouring System (AYON SYSTEM)

Indications for Use *(Describe)*
The AYON Body Contouring System is intended for the fragmentation, emulsification, and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring.

• The AYON Ultrasound Sub-System is used for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.

• The AYON Infiltration and Aspiration Sub-System(s) are used for the infiltration and suction / aspiration of fluids and tissue during surgical procedures. Infiltration and Suction is designed to operate as a stand-alone function.

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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510(k) SUMMARY

1. General Information

Submitted by:	Apyx Medical Corporation 5115 Ulmerton Road Clearwater, Florida 33760-4004 United States of America
Contact Person:	Angela Huber, PhD, RAC, Global Director of Regulatory Affairs Phone: 218-343-4881 Email: angela.huber@apyxmedical.com
Date Prepared:	May 5, 2025
Trade Name (Model Numbers):	**AYON™ Body Contouring System** (AYON SYSTEM)
Common Name:	Liposuction System
Classification:	Class II per 21CFR 878.5040 - Suction Lipoplasty System
Product Code	QPB
Predicate Device:	VASER 2.1 Lipo System (K110306)

2. Proposed Indications for Use

The AYON Body Contouring System is intended for the fragmentation, emulsification, and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring.

- The AYON Ultrasound Sub-System is used for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.
- The AYON Infiltration and Aspiration Sub-System(s) are used for the infiltration and suction / aspiration of fluids and tissue during surgical procedures. Infiltration and Suction is designed to operate as a stand-alone function.

3. Device Description

The AYON Body Contouring System includes an Ultrasound Sub-system, an Infiltration Sub-system, and an Aspiration Sub-system. The Ultrasound Sub-system includes an ultrasound amplifier, an ultrasound handpiece, and ultrasound probes which are to be used with compatible skin ports and plugs. The Infiltration Sub-system includes a peristaltic pump and weighing scale and utilizes sterile infiltration tubing, handles and cannulas to infiltrate tissue

with fluids. The Aspiration Sub-system includes two suction units that have the capability to function separately or together in series, such that it can be used as two separate suction units by two operators, or as a single suction unit (in series) by a single operator. The Aspiration Sub-system utilizes sterile suction tubing, handles and cannulas to aspirate fluids and soft tissue. The Infiltration and Aspiration Sub-systems are designed to operate independent of the Ultrasound Sub-system such that the system may be offered with only Infiltration and Aspiration to support standard suction-assisted liposuction (SAL) or with Ultrasound enabled to support ultrasound-assisted liposuction (UAL).

Apyx Medical devices/accessories for the system include the following:

- Infiltration and aspiration handles
- Ultrasound handpiece
- Ultrasound handpiece cables
- Ultrasound probes
- Footswitches: Two (2) wireless footswitches to control ultrasound and infiltration
- Skin ports and skin port tool
- AYON Base Tower mounting poles and canister mounts
- Power cords

Additional commercially available devices/accessories include the following:

- Infiltration and aspiration cannulas
- Aspiration filters
- Sterile, single-use infiltration and aspiration tubing
- Wrench
- Sterilization tray and cleaning brushes
- Collection canisters and liners
- Infiltration fluid warming unit(s)

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.

4. Performance Data

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

a. Mechanical and Physical Bench Testing

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

- The ultrasound subsystem was assessed for overall performance, tip vibrational amplitude, thermal effects on tissue, voltage and current outputs.
- The infiltration subsystem was assessed for overall performance, and compatibility with commercially available cannulas and tubing.
- The aspiration subsystem testing was performed in accordance with ISO 10079-1 and ISO 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 (direct and indirect contacting).

e. Reprocessing

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

5. Clinical Performance

No clinical studies were required to support the substantial equivalence of the device. These types of devices, including the predicate device, have been on the market for many years with proven safety and efficacy. 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. The identified Predicate Device is the Sound Surgical VASER 2.1 Lipo System, manufactured by Solta Medical under K110306. A comparison between the Subject Device and the Predicate Device is provided in Table 1.

Table 1. Substantial Equivalence Table

	AYON Body Contouring System Subject Device (This Submission)	VASER 2.1 Lipo System Predicate Device K110306	Comments
Overall System	**AYON Body Contouring System**	**VASER 2.1 Lipo System**	
Components of the System	Includes an Ultrasound Sub-System	Includes the Sound Surgical VASER 2.1 ultrasound system	Identical
	Includes an Aspiration Sub-System	Includes an aspiration system as part of the Sound Surgical VentX 2.1 system	Identical

	Includes an Infiltration Sub-System	Includes an infiltration system as part of the Sound Surgical VentX 2.1 system	Identical
Intended Use	Overall System: The AYON Body Contouring System is intended for the fragmentation, emulsification, and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring.	Overall System: The Sound Surgical VASER 2.1 Lipo System is intended for the fragmentation, emulsification and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring.	Identical
	Overall System:	Overall System: The Sound Surgical VASER 2.1 Lipo System is also indicated for use in the following surgical specialties for the fragmentation, emulsification and aspiration of soft tissue: • Neurosurgery; • Gastrointestinal and affiliated organ surgery; • Urological surgery; • Plastic and reconstructive surgery; • General surgery; • Gynecological surgery; • Thoracic surgery; and • Laparoscopic surgery.	The Subject Device is not pursuing the expanded indications for additional surgical specialties included in the intended use for the Predicate Device.
	Ultrasound Sub-System: The AYON Ultrasound Sub-System is used for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.	Ultrasound Sub-System: The Sound Surgical VASER 2.1 is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.	Same intent and purpose of use with minor changes.
	Infiltration and Aspiration Sub-Systems: The AYON Infiltration and Aspiration Sub-System(s) are used for the infiltration and suction / aspiration of fluids and tissue during surgical procedures. Infiltration and Suction is designed to operate as a stand-alone function.	Infiltration and Aspiration Sub-Systems: The Sound Surgical VentX 2.1 is intended for the suction or aspiration of fluids and tissue during surgical procedures. The VentX 2.1 is designed to operate with the Sound Surgical VASER 2.1 or as a stand-alone system.	Same intent and purpose of use with minor changes for clarity.

Product Code /Regulation	QPB, 21 CFR 878.5040	QPB, 21 CFR 878.5040	Identical
User	Used by trained Physicians in an operating environment.	Used by trained Physicians in an operating environment.	Identical
Mechanism of Action	The ultrasound system fragments and emulsifies subcutaneous fatty tissue. The infiltration and aspiration systems utilize sterile infiltration tubing, a handle and cannula to infiltrate the tissue with fluids, and sterile suction tubing, a handle and cannula to aspirate fluids and soft tissue.	The ultrasound system fragments and emulsifies subcutaneous fatty tissue. The infiltration and aspiration systems utilize sterile infiltration tubing, a handle and cannula to infiltrate the tissue with fluids, and sterile suction tubing, a handle and cannula to aspirate fluids and soft tissue.	Identical
User Interface/Controls	Single touchscreen utilizing a graphical user interface, on/off switches	Knobs and dials in various locations, on/off switches.	The single touchscreen of the Subject Device enables ease of use through control of the entire system in one centralized location.
Ultrasound Sub-System			
Voltage and Frequency	AC Powered Voltage: 100-120 VAC Frequency: 60/50 Hz	AC Powered Voltage: 115C/230VAC Frequency: 60/50 Hz	Similar
Electrical Safety	IEC Class I, Type BF	IEC Class I, Type BF	Identical
Method of Fragmentation and Emulsification	Ultrasonic	Ultrasonic	Identical
Operating Frequency	37 kHz nominal	36 kHz nominal	Similar
Ultrasound Handpiece Transducer Material	Piezoelectric crystal	Piezoelectric crystal	Identical
Ultrasound Probes	Types: Diameters – 2.2mm to 3.7mm Lengths – 18cm to 33cm	Types: Diameters – 1.0mm to 6.0mm Lengths – 7cm to 40cm	Similar
	Material: Titanium alloy	Material: Titanium alloy	Identical
Ultrasound Vibratory Power / Amplitude	Three different power or amplitude settings: Low power = 8 watts Medium power = 20 watts	Power or amplitude settings ranging from 10% to 100%	Similar

	High power = 28 watts		
Modes of Operation	Standard Mode - Delivers the ultrasonic energy in pulses of two different amplitudes. The pulses alternate between full amplitude for 50 milliseconds and an amplitude of 50% of the full amplitude for 50 milliseconds.	VASER (Pulse) Mode - Delivers the ultrasonic energy in pulses of two different amplitudes. The pulses alternate between full amplitude for 50 milliseconds and an amplitude of 50% of the full amplitude for 50 milliseconds.	Identical
	Continuous Mode – Delivers the ultrasonic energy continuously at full amplitude.	Continuous Mode – Delivers the ultrasonic energy continuously at full amplitude.	Identical
Aspiration Sub-System			
Power	AC Powered Voltage: 120 VAC Frequency: 50-60 Hz Power: 950 VA	AC Powered Voltage 120 VAC Frequency 60 Hz Power: 1000 VA	Similar
Electrical Safety	IEC Class I, Type BF	IEC Class I, Type BF	Identical
Suction Vacuum	27 in Hg at sea level	20 in Hg at 5000 ft. (~25 in Hg at sea level)	Similar [1]
Infiltration Sub-System			
Power	AC Powered Voltage: 120 VAC Frequency: 50-60 Hz Power: 950 VA	AC Powered Voltage 120 VAC Frequency 60 Hz Power: 1000 VA	Similar
Electrical Safety	IEC Class I, Type BF	IEC Class I, Type BF	Identical
Infiltration Pump	Peristaltic	Peristaltic	Identical
Infiltration Rate	Adjustable flow rate from 40-1000mL/min	Adjustable flow rate from 50-550mL/min	Similar[2]

7. Substantial Equivalence Determination

The Subject and Predicate Devices have the same intended use, the minor clarifications do not change safety of the device or use of the device. The devices have identical mechanisms of action to produce the fragmentation and emulsification of subcutaneous fatty tissues. The technological features of the two devices are either identical or very similar in nature. Minor differences in the Ultrasound Sub-systems were found not to have an impact on the substantial equivalence of the two devices through comparative bench testing. Based on the information contained in this submission, it is concluded that the AYON Body Contouring System is substantially equivalent in function and intended use to the identified predicate device, the Sound Surgical VASER 2.1 Lipo System, manufactured by Solta Medical under

[1] Suction vacuum for the Subject Device falls within the vacuum range of 0 to 29.9 in Hg included in the Product Code description and falls below the maximum vacuum range for other FDA cleared devices. Vitruvian Ultimate Aspirator (K161722), PSI-TEC Aspirator (K981215).

[2] The infiltration flow rates for the Subject Device are identical or fall below the maximum flow rates for other FDA cleared infiltration and infusion pumps. Reference devices; Klein Surgical Infiltration pump (K031432) and the Wells Johnson Infusion pump (K991437).

K110306.

8. Conclusion

The performance data presented in this submission, supports substantially equivalent performance between the subject device and its predicate.