



December 30, 2024

MicroAire Surgical Instruments, LLC
Heather Crilly
Senior Regulatory Affairs Specialist
3590 Grand Forks Blvd.
Charlottesville, Virginia 22911

Re: K242804

Trade/Device Name: PAL[®] Aspiration System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB
Dated: September 17, 2024
Received: December 5, 2024

Dear Heather Crilly:

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

Digitally signed by Alicia Hemphill -S

-S

Date: 2024.12.30 20:29:46 -06'00'

Alicia L. Hemphill, M.S.

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

510(k) Number (if known)
K242804

Device Name
PAL® Aspiration System

Indications for Use (Describe)

Aesthetic body contouring

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for MicroAire PAL Aspiration System is provided below:

1. Submitter

MicroAire® Surgical Instruments, LLC.
3590 Grand Forks Boulevard
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USA

2. Primary Contact Person

Heather Crilly
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3. Date Prepared

August 30, 2024

4. Device Identification

Trade/Proprietary Name:	PAL® Aspiration System
Common/Usual Name:	Aspiration System
Regulation Number:	21 CFR 878.5040
Regulation Name:	Suction lipoplasty system
Regulatory Class:	Class II
Product Code:	QPB
Classification Panel:	General and Plastic Surgery Devices

5. Predicate Device

Primary Predicate

Device name: K161722, Black & Black Surgical, Inc. Vitruvian Ultimate Aspirator
This predicate has not been subjected to a design-related recall.

6. Device Description

The MicroAire PAL® Aspiration System provides an adjustable vacuum source that drives the suction of tissue during suction-assisted aesthetic body contouring procedures.

The PAL Aspiration System features a modular style PAL® Aspiration Pump (ASP-PUMP-120/240) unit with a separate, stackable PAL® Aspiration Pump Console (ASP-UI) which provides organizational modularity and ease of transport within the medical facility. Communication between the units is achieved via the Aspiration Pump Cable (ASP-CBL).

The PAL Aspiration Pump utilizes a dual-piston pump as a vacuum source that delivers 0-29 inHg and drives the suction of tissue. The PAL Aspiration Pump also features a multi-socket outlet (MSO) to provide power to up to four devices using the AC Power Cord Jumper Cable (ASP-CORD), eliminating extra power cords for better cable organization.

The PAL Aspiration Pump Console is an electronic control system which allows the operator to digitally set and visualize the vacuum level. It also provides the status of basic pump operations, sends the Pump's ON/OFF signal, and provides receptacles for the connection of the Aspiration Pump Cable and optional accessories.

The Aspiration Foot Switch (ASP-FOOT) and the 5020 to Aspiration Pump Cable (5020-ASP) are optional accessories which provide the operator with additional Aspiration Pump ON/OFF control options.

The PAL Aspiration Pump requires a Biofilter (ASP-FLTR2), which prevents the ingress of vapor particulate into the motor. The Biofilter is a non-sterile filter assembly with vacuum tubing placed on the vacuum inlet. Connection to a system of generic collection canisters (sold separately) is expected for the PAL Aspiration System to function as intended. Additional Vacuum Tubing (ASP-TUBING) can be used to replace existing Biofilter tubing as needed.

7. Indications for Use Statement

Aesthetic body contouring.

8. Substantial Equivalence Comparison

The following Table A compares the subject device MicroAire Surgical PAL® Aspiration System with the predicate device Black & Black Surgical Vitruvian Ultimate Aspirator (K161722) with respect to indications for use, mechanisms of operation, technological characteristics, materials, and performance testing forming the basis for the determination of substantial equivalence. The differences in the subject device as compared to the predicate device do not raise any new questions of safety or effectiveness.

Table A

Comparison to Predicate

Characteristic	Predicate Device Vitruvian Ultimate Aspirator, K161722	Subject Device MicroAire, TBD	Device Comparison
CLASSIFICATION & INDICATIONS			
FDA Classification	Class II	Class II	Same
FDA Product Code	QPB	QPB	Same
FDA Classification Name	Suction Lipoplasty System	Suction Lipoplasty System	Same
Indications for Use	Aesthetic body contouring	Aesthetic body contouring	Same
Intended Use	Aesthetic body contouring	Aesthetic body contouring	Same
SUMMARY OF PHYSICAL CHARACTERISTICS			
Housing	Powder Coated Steel	Powder Coated Steel	Same
Dimensions	LxWxH: 18"x18"x38"	ASP-PUMP-XXX (LxWxH): 18.5"x15.8"x13.5" ASP-UI (LxWxH): 14.0"x12.1"x5.2"	Similar
Weight	100 lb	Pump = 67 lb Control = 10 lb	Similar
IV Pole for Solutions	IV Pole + Mount	None	Different
Filter Port	Yes	Yes	Same
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS			
Pump Type	Two-cylinder piston	Two-cylinder piston	Same
AC Power input	120V, 60Hz 230V, 50Hz	115V, 60Hz (ASP-PUMP-120) 230V, 50Hz (ASP-PUMP-240)	Similar
Display	Vacuum gauge w/ LED color graphic readout. Displays the current vacuum pressure in graphical (for inHg and mmHg) and digital (for inHg) format.	Non-touchscreen LCD digital readout of vacuum pressure (inHg and mmHg), target vacuum pressure settings, and Biofilter operational hours; as well as Information Signals to inform the user when to change the Biofilter, motor overtemp condition, and if the Pump is not functioning.	Different
Pressure Control	Knob to control vacuum	Knob to control vacuum and optional programmable membrane switches on Pump Control interface to preset/user defined values.	Different

Footswitch	Dual activated air powered	Dual electric powered	Different
Remote Wired Activation	N/A	Remote wired ON/OFF vacuum Pump activation through MicroAire 5020 Console (component of Reference Device PAL System, K212024).	Different
Safety Features (overflow valve)	Manual (canister)	Internal catch-can with fluid sensor cutoff	Similar
Filter Size	0.3 Micron	0.22 Micron	Similar
Maximum Vacuum	27.5 inHg	29 inHg	Different; see reference device comparison in Table B
Maximum Flow Rate	6.4 cfm	2.12 cfm (60L/min) @ 60Hz 1.77 cfm (50L/min) @ 50Hz	Different
Sound Level	50 dB	56.8 dBA	Similar

9. Performance Data

Non-clinical testing was performed to verify and validate the design of the PAL® Aspiration System against specified design requirements and to assure conformance with applicable recognized national consensus standards and FDA Guidance documents. The PAL Aspiration System passed all non-clinical bench testing, supporting its safety and effectiveness, and its substantial equivalence to the predicate device.

The PAL Aspiration System complies with all applicable voluntary consensus standards and FDA Guidance documents for electrical safety, electromagnetic compatibility, and safety of electrically powered suction pumps:

- Electrical safety testing per IEC 60601-1
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 and IEC 60601-4-2

- Essential Performance per IEC 60601-1-6
- Software Verification per IEC 62304
- Usability testing per IEC 62366-1
- Safety testing for electrically powered suction pumps per ISO 10079-1
- Bench Testing demonstrated that the specifications for vacuum performance, free air flow, noise, and reliability were met.

10. Clinical Performance Data

The PAL Aspiration System has not been the subject of clinical testing.

11. Conclusion

The Black & Black Vitruvian Ultimate Aspirator (K161722) and the MicroAire PAL® Aspiration System share the same Indications for Use, Intended Use, and similar overall technical and functional capabilities, and therefore the PAL Aspiration System demonstrates substantially equivalence to the predicate device.