MicroAire Surgical Instruments
% Diane Sudduth
Sr. Consultant, Regulatory
Barile & Associates, Inc.
PO Box 5199
Clinton, New Jersey 08809

June 9, 2021

Re: K192694
Trade/Device Name: PAL Single-Use Cannulas
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Diane Sudduth:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 14, 2020. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

May 14, 2020

MicroAire Surgical Instruments
% Diane Sudduth
Sr. Consultant, Regulatory
Barile & Associates, Inc.
PO Box 5199
Clinton, New Jersey 08809

Re: K192694
Trade/Device Name: PAL Single-Use Cannulas
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: April 6, 2020
Received: April 8, 2020

Dear Ms. Sudduth:

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,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192694

Device Name
MicroAire® PAL® Single-Use Cannulas

Indications for Use *(Describe)*
MicroAire® PAL® Single-Use Cannulas are 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510K Summary

PAL® Single-Use Cannulas
K 192694

1. Submission Sponsor

MicroAire Surgical Instruments
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911
USA
Office Phone: (434) 975-8344
Email: glenn.gerstenfeld@microaire.com
Contact: Glenn Gerstenfeld
Title: Vice President, QA/RA and Compliance Officer

2. Submission Correspondent

Barile & Associates, Inc.
PO Box 5199
Clinton, NJ 08809
Office Phone: (561) 305-5075
Email: drsudduth05@gmail.com
Contact: Diane Sudduth, Ph.D.
Title: Senior Consultant, RA

3. Date Prepared

September 20, 2019 (amended April 21, 2020)

4. Device Identification

Trade/Proprietary Name:	PAL® Single-Use Cannulas
Common/Usual Name:	Cannula
Classification Name:	Suction Lipoplasty System
Regulation Number:	21 CFR 878.5040
Product Code:	MUU
Device Class:	Class II
Classification Panel:	GENERAL AND PLASTIC SURGERY DEVICES

5. Legally Marketed Predicate Device(s)

Predicate Device:	K171286, MicroAire® PAL System, Multi-Use Cannula
Classification Name:	Suction Lipoplasty System
Regulation Number:	21 CFR 878.5040
Product Code:	MUU
Classification:	Class II

Reference Device:	K981922, MicroAire® Power Aspiration Device (PAD) System Cannula
Classification Name:	Suction Lipoplasty System,
Regulation Number:	21 CFR 878.5040
Product Code:	MUU
Classification:	Class II

6. Indication for Use Statement

The MicroAire PAL Single-Use Cannulas are 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.

7. Device Description

The MicroAire® PAL liposuction family of instruments is intended to be used 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 MicroAire® PAL Single-Use Cannulas consists of stainless-steel cannula with a plastic hub which attaches to the MicroAire® PAL-730 Manual Wand and has a connection for a standard vacuum (suction) tubing. The MicroAire® Single-Use Cannulas are supplied sterile by the manufacturer through a validated gamma irradiation process. The Single-Use Cannula are offered in various diameters (2.4, 3.0, 4 and 5.0mm diameters), lengths (15, 22, and 30 cm) and with various types of distal fenestrations (Single Port, Mercedes, Flared Mercedes, Bent Flared Mercedes, Double Mercedes, Bent Mercedes, Tri-Port II, Tri-Port III, Helixed Tri-Port III, Spatula, Multi-Hole, Del Vecchio Track-12).

8. Substantial Equivalence Discussion

The following table compares the MicroAire PAL Single-Use Cannulas to the predicate device MicroAire PAL Multi-Use Cannulas and the reference device MicroAire PAD System Cannula with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics with Predicate Device

Manufacturer	**MicroAire Surgical Instruments**		**Comparison**
Trade Name	**MicroAire PAL Single-Use Cannula**	**MicroAire PAL Multi-Use Cannula**	
510k Number	K192694	K171286	N/A
Product Code	MUU	MUU	Same
Regulation Number	21 CFR 878.5040	21 CFR 878.5040	Same
Regulation Name	Suction Lipoplasty System	Suction Lipoplasty System	Same
Indications for Use	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	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	Same
Performance Characteristics	• Designed to be used with the PAL-730 Manual Wand • Available in 2.4mm, 3mm, 4mm and 5mm Diameters • Available in 15cm, 22cm, and 30cm Lengths	• Designed to be used with the PAL-730 Manual Wand • Available in 2.4mm, 3mm, 4mm and 5mm Diameters • Available in 15cm, 22cm, 30cm and 40cm Lengths	Similar; multi-use available in 40cm length
Available Fenestration types	Single Port, Mercedes, Flared Mercedes, Double Mercedes, Tri-port II, Mirrored Tri-port, Tri-port III, Spatula, Track-12, Helixed Tri-Port, Spatula, Multi-Hole, Bent Mercedes, Bent Flared Mercedes	Mercedes, Flared Mercedes, Double Mercedes, Tri-port II, Mirrored Tri-port, Tri-port III, Spatula, Track-12, Helixed Tri-Port, Multi-Hole, Bent Mercedes, Bent Flared Mercedes	Similar; single-use available in single port and spatula fenestration type
Function	Used for removal of tissue or fluid from the body during general surgical procedures including suction Lipoplasty for the purpose of aesthetic body contouring	Used for removal of tissue or fluid from the body during general surgical procedures including suction Lipoplasty for the purpose of aesthetic body contouring	Same
Mechanism of action	The cannulas attach to the PAL-730 Manual Wand and suction tubing via a cannula hub. This tubing connects to an external suction source (not part of the PAL System).	The cannulas attach to the PAL-730 Manual Wand and suction tubing via a cannula hub. This tubing connects to an external suction source (not part of the PAL System).	Same

Manufacturer	**MicroAire Surgical Instruments**		**Comparison**
Trade Name	**MicroAire PAL Single-Use Cannula**	**MicroAire PAL Multi-Use Cannula**	
	Fluid and tissue are removed from the body via the tubing assisted by the external suction source. The handpiece is not powered and does not reciprocate.	Fluid and tissue are removed from the body via the tubing assisted by the external suction source. The handpiece is not powered and does not reciprocate.	
Material	Cannula is a blunt tipped hollow tube comprised of 304 stainless steel. Cannula Hub is comprised of a Release Tab, made of Dupont Zytel ST801 (nylon), a turbo plug made of Silicon 70 Blue, USP Class VI, and the hub itself made of Polystyrene 825 bonded together with cyanoacrylate adhesive	Cannula is a blunt tipped hollow tube comprised of 304 stainless steel. Cannula Hub is comprised of a Release Tab, made of Dupont Zytel ST801 (nylon), a Dowel Pin, made of 410 or 416 or 18-8 Stainless Steel, and the hub itself made of Vectra MT1310 bonded together with cyanoacrylate adhesive	Similar; hub material is polystyrene vs. Vectra MT1310
Sterile	Supplied Sterile; Gamma Irradiation	Supplied non-sterile; Steam Sterilized by end user	Different; single-use is supplied gamma sterilized
Single-Use	Yes	No	Different
Shelf Life	1 year	N/A	Different
Complies with ISO 10993-1	Yes	Yes	Same

Table 5B – Comparison of Characteristics with Reference Device

Manufacturer	**MicroAire Surgical Instruments**		**Comparison**
Trade Name	**MicroAire PAL Single-Use Cannula**	**MicroAire PAD System Cannula**	
510k Number	K192694	K981922	N/A
Product Code	MUU	MUU	Same
Regulation Number	21 CFR 878.5040	21 CFR 878.5040	Same
Regulation Name	Suction Lipoplasty System	Suction Lipoplasty System	Same

Manufacturer	**MicroAire Surgical Instruments**		**Comparison**
Trade Name	**MicroAire PAL Single-Use Cannula**	**MicroAire PAD System Cannula**	
Indications for Use	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	For the removal of tissue or fluid from the body during general surgical procedures, including suction lipoplasty, for the purpose of aesthetic body contouring	same
Function	Used for removal of tissue or fluid from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring	Used for removal of tissue or fluid from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring	Same
Material	Cannula is a blunt tipped hollow tube comprised of 304 stainless steel. Cannula Hub is comprised of a Release Tab, made of Dupont Zytel ST801 (nylon), a turbo plug made of Silicon 70 Blue, USP Class VI, and the hub itself made of Polystyrene 825 bonded together with cyanoacrylate adhesive	Cannula is a blunt tipped hollow tube comprised of 304 stainless steel with an attached PVC suction tube and optional syringe. The cannula hub is comprised of a Release Tab, made of Dupont Zytel ST801 (nylon) and the hub is made of Polystyrene 825.	same
Sterile	Supplied Sterile; Gamma Irradiation	Supplied sterile; gamma irradiation	same
Single-Use	Yes	Yes	Same
Shelf Life	1 year	4 years	Similar; testing is ongoing to support a 4-year shelf life for the Single-Use Cannula, however, was not available at the time of submission
Complies with ISO 10993-1	Yes	Yes	Same

The PAL Single-Use Cannulas share the same indications for use, and same or similar device operation, overall technical and functional capabilities, and therefore are substantially equivalent to the predicate and reference devices. The PAL Single-Use Cannulas are similar in design and function to

the predicate and reference devices for the modes of operation and use. The PAL Single-Use Cannulas share the same indications for use, and same or similar device operation, overall technical and functional capabilities, and follow those of the reference device. The PAL Single-Use Cannula is sterilized by gamma irradiation, equal to the reference device.

9. Non-Clinical Performance Data

The following tests were performed to demonstrate that the proposed MicroAire PAL Single-Use Cannulas met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

- Sterilization validation per ISO 11137 – demonstrates SAL of 10^{-6}
- Biocompatibility testing – Cytotoxicity, Sensitization, Irritation, per ISO 10993 - PASSED

In addition to the guidance and standards testing, the following testing was performed:

- Mechanical Tensile Testing (fatigue, axial strength, pullout force, pushout force, bend) – Met specifications
- Air leakage and tubing connection force test – Met specifications
- Vacuum pressure testing – Met specification
- Transportation Testing per ASTM D4169 – demonstrates package integrity maintained

10. Statement of Substantial Equivalence – Conclusions Drawn

The MicroAire PAL® Single-Use Cannulas, as designed and manufactured, are determined to be substantially equivalent to the predicate and reference devices. Nonclinical testing demonstrates the subject device is substantially equivalent to the legally marked predicate and reference devices.