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

June 9, 2021

Re: K171286
Trade/Device Name: PAL Multi-Use Cannulas and PAL Manual Wand
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 October 13, 2017. 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

October 13, 2017

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

Re: K171286
Trade/Device Name: PAL Multi-Use Cannulas and PAL Manual Wand
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: September 11, 2017
Received: September 12, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MicroAire PAL Multi-Use Cannula and PAL-730 Manual Wand

Indications for Use *(Describe)*
The MicroAire PAL Manual Wand and Multi 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.

510(k) Summary

PAL Multi-Use Cannula and PAL Manual Wand

K171286

1. Submission Sponsor

MicroAire® Surgical Instruments, Inc.
3590 Grand Forks Boulevard
Charlottesville
Virginia, 22911
USA
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
Contact: Diane Sudduth
Title: Senior Consultant, RA

3. Date Prepared

April 28, 2017

4. Device Identification

Trade/Proprietary Name:	PAL Multi-Use Cannula and PAL Manual Wand
Common/Usual Name:	Cannula and wand or handpiece
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: 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

Reference Device #1: K113795, Black& Black Surgical Inc., Aspiration and Infiltration Cannulas

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 Manual Wand and Multi-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 indicated for use 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 Multi-Use Cannula consists of a stainless steel cannula with a plastic hub which attaches to the MicroAire® PAL-730 Manual Wand and has a connection for standard vacuum (suction) tubing.

The MicroAire® Multi-Use Cannula is supplied non-sterile to be sterilized by the user, and may be steam sterilized for use on subsequent patients. The Multi-Use Cannula are offered in various diameters (2.4mm, 3.0mm, 4.0mm and 5.0mm diameters), lengths (15cm, 22cm, 30cm and 40 cm) and with various types of distal fenestrations (Mercedes, Flared Mercedes, 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).

The MicroAire® PAL Manual Wand (PAL-730) is indicated for use in 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 Multi-Use Cannulas are supplied non-sterile to be sterilized by the user prior to use, and may be steam sterilized for use on subsequent patients

8. Substantial Equivalence Discussion

The following table compares the characteristics of the MicroAire® PAL Multi-Use Cannula with those of the predicate 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 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. Below is a portion of the comparison of devices.

Table 5A - Comparison of Characteristics

Manufacturer	MicroAire Surgical Instruments, Inc.		MicroAire Surgical Instruments, Inc.		Black & Black Surgical Inc.
Trade Name	MicroAire® PAL Multi-Use Cannula	MicroAire® PAL Manual Wand	MicroAire® PAD System Cannula	MicroAire® PAD System Handpiece	Aspiration and Infiltration Cannulas
510k Number	-	-	K981922	K981922	K113795
Product Code	MUU	MUU	MUU	MUU	MUU, GEA
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	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	The aspiration and infusion cannulas and needles are indicated for aesthetic body contouring and general tissue aspiration
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, 30cm and 40cm Lengths	Designed to be used with PAL Multi-Use Cannulas	Designed to be used with the PAD pneumatic or electric reciprocating handpiece which attaches to the cannula via a hub.	Designed to be used with PAD Single Use Cannulas	Designed to be used with a manual liposuction handpiece with either a Luer Lock Hub or a Syringe hub Available in 2mm, 3mm, 4mm, 5mm and 6mm Diameters Available in 15cm, 20cm, 26cm, 32cm and 36cm Lengths
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). Fluid and tissue is removed from the body via the tubing assisted by the external suction source.	The handpiece attaches to a Multi-Use Cannula and suction tubing via a cannula hub. The tubing connects to an external suction source (not part of the PAL System). Fluid and tissue is removed from the body via the suction tubing assisted by the external suction source. The handpiece is not powered and does not reciprocate.	The cannulas attach to the PAD pneumatic or electric reciprocating handpiece and suction tubing via a cannula hub. The disposable cannula with attached suction tubing connects to an external suction source that is not part of the PAD system.	The handpiece attaches to the disposable cannula and suction tubing via a cannula hub. The tubing connects to an external suction source (not part of the PAD System). The reciprocating handpiece drives the cannula through a stroke distance of 2.4-6mm at a rate of 4000 strokes per minute minimum. The device is powered by a console and cable	The cannulas remove fluid, soft tissue and exudates and the needles infusion fluid by using a hollow stainless steel tube, multiple tips, a handle and attachment connector that are used in reusable and disposable configurations.

Material	Cannula is comprised of a blunt-tipped hollow tube of 304 stainless steel. The Cannula hub is comprised of Vectra MT1310 with a Release Tab made of Dupont Zytel ST801 (nylon), and a Dowel Pin made of 410 or 416 Stainless Steel	Anodized aluminum and stainless steel	Cannula is comprised of a blunt-tipped hollow tube of 304 stainless steel with an attached PVC suction tube and optional syringe. The Cannula hub is comprised of Polystyrene 825 with a Release Tab made of Dupont Zytel ST801 (nylon)	Anodized Aluminum and Stainless Steel	Cannula and Needles are manufactured of stainless steel tubes with aluminum handles. The patient-contacting material is stainless steel
Sterile	Supplied non-sterile; Steam Sterilized by end user	Supplied non-sterile; Steam Sterilized by end user	Supplied Sterile; Gamma Irradiation	Supplied non-sterile; Steam Sterilized by end user	Supplied non-sterile; Steam Sterilized by end user
Single-Use	No	No	Yes	No	No
Shelf Life	N/A	N/A	4 years	5 years	N/A
Complies with ISO 10993-1	Yes	Yes	Yes	Yes	Yes

9. Non-Clinical Performance Data

As part of demonstrating the safety and effectiveness of MicroAire® PAL Multi-Use Cannula and PAL Manual wand in showing substantial equivalence, MicroAire completed a number of non-clinical performance tests. The PAL Multi-Use Cannula meets all the requirements for overall design, sterilization and biocompatibility results confirming that the design output meets the design input and specifications for the device.

The MicroAire® PAL Multi-Use Cannula and Pal Manual Wand passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1
- Bending Strength – meets all internal specification requirements, see Section 18
- Fatigue Testing – meets all internal specification requirements, see Section 18
- Pullout and Force Testing – meets all internal specification requirements, see Section 18
- Compression Testing – meets all internal specification requirements, see Section 18
- Cleaning – conducted per FDA guidance dated March 17, 2015
- Sterilization – conducted per AAMI TIR12:2010; ANSI/AAMI/ISO 17665-1: 2006 (EN ISO 17665-1: 2006); ANSI/AAMI ST79:2010/A1:2010/A2:2011/A3:2012/A4:2013/®2014; FDA guidance for reprocessing medical devices dated March 17, 2015.
- Shelf Life Testing – N/A (device provided non-sterile); see Section 14
- Storage and Distribution Testing – meets internal specification requirements, See Section 14

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Conclusion Statement of Substantial Equivalence

MicroAire® PAL Multi-Use Cannula and PAL Manual Wand is substantially equivalent to predicate devices MicroAire® PAD system Cannula + Handpiece, as well as the Black and Black Aspiration Cannulas wherein the device has the same intended use to the predicate even with slightly different design characteristics, the new device does not raise additional questions regarding safety and effectiveness as compared to the predicate device(s). The testing completed support this claim.

The MicroAire® PAL Multi-Use Cannula, as designed and manufactured, is deemed to be substantially equivalent to the referenced predicate device(s).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MicroAire PAL Multi-Use Cannula and PAL-730 Manual Wand

Indications for Use *(Describe)*
The MicroAire PAL Manual Wand and Multi 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.

October 13, 2017

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

Re: K171286
Trade/Device Name: PAL Multi-Use Cannulas and PAL Manual Wand
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: September 11, 2017
Received: September 12, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MicroAire PAL Multi-Use Cannula and PAL-730 Manual Wand

Indications for Use *(Describe)*
The MicroAire PAL Manual Wand and Multi 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.

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510(k) Summary

PAL Multi-Use Cannula and PAL Manual Wand

K171286

1. Submission Sponsor

MicroAire® Surgical Instruments, Inc.
3590 Grand Forks Boulevard
Charlottesville
Virginia, 22911
USA
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
Contact: Diane Sudduth
Title: Senior Consultant, RA

3. Date Prepared

April 28, 2017

4. Device Identification

Trade/Proprietary Name:	PAL Multi-Use Cannula and PAL Manual Wand
Common/Usual Name:	Cannula and wand or handpiece
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: 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

Reference Device #1: K113795, Black& Black Surgical Inc., Aspiration and Infiltration Cannulas

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 Manual Wand and Multi-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 indicated for use 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 Multi-Use Cannula consists of a stainless steel cannula with a plastic hub which attaches to the MicroAire® PAL-730 Manual Wand and has a connection for standard vacuum (suction) tubing.

The MicroAire® Multi-Use Cannula is supplied non-sterile to be sterilized by the user, and may be steam sterilized for use on subsequent patients. The Multi-Use Cannula are offered in various diameters (2.4mm, 3.0mm, 4.0mm and 5.0mm diameters), lengths (15cm, 22cm, 30cm and 40 cm) and with various types of distal fenestrations (Mercedes, Flared Mercedes, 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).

The MicroAire® PAL Manual Wand (PAL-730) is indicated for use in 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 Multi-Use Cannulas are supplied non-sterile to be sterilized by the user prior to use, and may be steam sterilized for use on subsequent patients

8. Substantial Equivalence Discussion

The following table compares the characteristics of the MicroAire® PAL Multi-Use Cannula with those of the predicate 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 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. Below is a portion of the comparison of devices.

Table 5A - Comparison of Characteristics

Manufacturer	MicroAire Surgical Instruments, Inc.		MicroAire Surgical Instruments, Inc.		Black & Black Surgical Inc.
Trade Name	MicroAire® PAL Multi-Use Cannula	MicroAire® PAL Manual Wand	MicroAire® PAD System Cannula	MicroAire® PAD System Handpiece	Aspiration and Infiltration Cannulas
510k Number	-	-	K981922	K981922	K113795
Product Code	MUU	MUU	MUU	MUU	MUU, GEA
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	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	The aspiration and infusion cannulas and needles are indicated for aesthetic body contouring and general tissue aspiration
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, 30cm and 40cm Lengths	Designed to be used with PAL Multi-Use Cannulas	Designed to be used with the PAD pneumatic or electric reciprocating handpiece which attaches to the cannula via a hub.	Designed to be used with PAD Single Use Cannulas	Designed to be used with a manual liposuction handpiece with either a Luer Lock Hub or a Syringe hub Available in 2mm, 3mm, 4mm, 5mm and 6mm Diameters Available in 15cm, 20cm, 26cm, 32cm and 36cm Lengths
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). Fluid and tissue is removed from the body via the tubing assisted by the external suction source.	The handpiece attaches to a Multi-Use Cannula and suction tubing via a cannula hub. The tubing connects to an external suction source (not part of the PAL System). Fluid and tissue is removed from the body via the suction tubing assisted by the external suction source. The handpiece is not powered and does not reciprocate.	The cannulas attach to the PAD pneumatic or electric reciprocating handpiece and suction tubing via a cannula hub. The disposable cannula with attached suction tubing connects to an external suction source that is not part of the PAD system.	The handpiece attaches to the disposable cannula and suction tubing via a cannula hub. The tubing connects to an external suction source (not part of the PAD System). The reciprocating handpiece drives the cannula through a stroke distance of 2.4-6mm at a rate of 4000 strokes per minute minimum. The device is powered by a console and cable	The cannulas remove fluid, soft tissue and exudates and the needles infusion fluid by using a hollow stainless steel tube, multiple tips, a handle and attachment connector that are used in reusable and disposable configurations.

Material	Cannula is comprised of a blunt-tipped hollow tube of 304 stainless steel. The Cannula hub is comprised of Vectra MT1310 with a Release Tab made of Dupont Zytel ST801 (nylon), and a Dowel Pin made of 410 or 416 Stainless Steel	Anodized aluminum and stainless steel	Cannula is comprised of a blunt-tipped hollow tube of 304 stainless steel with an attached PVC suction tube and optional syringe. The Cannula hub is comprised of Polystyrene 825 with a Release Tab made of Dupont Zytel ST801 (nylon)	Anodized Aluminum and Stainless Steel	Cannula and Needles are manufactured of stainless steel tubes with aluminum handles. The patient-contacting material is stainless steel
Sterile	Supplied non-sterile; Steam Sterilized by end user	Supplied non-sterile; Steam Sterilized by end user	Supplied Sterile; Gamma Irradiation	Supplied non-sterile; Steam Sterilized by end user	Supplied non-sterile; Steam Sterilized by end user
Single-Use	No	No	Yes	No	No
Shelf Life	N/A	N/A	4 years	5 years	N/A
Complies with ISO 10993-1	Yes	Yes	Yes	Yes	Yes

9. Non-Clinical Performance Data

As part of demonstrating the safety and effectiveness of MicroAire® PAL Multi-Use Cannula and PAL Manual wand in showing substantial equivalence, MicroAire completed a number of non-clinical performance tests. The PAL Multi-Use Cannula meets all the requirements for overall design, sterilization and biocompatibility results confirming that the design output meets the design input and specifications for the device.

The MicroAire® PAL Multi-Use Cannula and Pal Manual Wand passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1
- Bending Strength – meets all internal specification requirements, see Section 18
- Fatigue Testing – meets all internal specification requirements, see Section 18
- Pullout and Force Testing – meets all internal specification requirements, see Section 18
- Compression Testing – meets all internal specification requirements, see Section 18
- Cleaning – conducted per FDA guidance dated March 17, 2015
- Sterilization – conducted per AAMI TIR12:2010; ANSI/AAMI/ISO 17665-1: 2006 (EN ISO 17665-1: 2006); ANSI/AAMI ST79:2010/A1:2010/A2:2011/A3:2012/A4:2013/®2014; FDA guidance for reprocessing medical devices dated March 17, 2015.
- Shelf Life Testing – N/A (device provided non-sterile); see Section 14
- Storage and Distribution Testing – meets internal specification requirements, See Section 14

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Conclusion Statement of Substantial Equivalence

MicroAire® PAL Multi-Use Cannula and PAL Manual Wand is substantially equivalent to predicate devices MicroAire® PAD system Cannula + Handpiece, as well as the Black and Black Aspiration Cannulas wherein the device has the same intended use to the predicate even with slightly different design characteristics, the new device does not raise additional questions regarding safety and effectiveness as compared to the predicate device(s). The testing completed support this claim.

The MicroAire® PAL Multi-Use Cannula, as designed and manufactured, is deemed to be substantially equivalent to the referenced predicate device(s).