10/14/2022

MicroAire Surgical Instruments, LLC
Glenn Gerstenfeld
Vice President, QA/RA and Compliance Officer
3590 Grand Forks Blvd
Charlottesville, Virginia 22911

Re: K220318
Trade/Device Name: PAL Infiltration System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: QPB
Dated: June 19, 2022
Received: June 21, 2022

Dear Glenn Gerstenfeld:

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,

Deborah Fellhauer RN, BSN
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220318

Device Name
MicroAire PAL Infiltration System

Indications for Use *(Describe)*
The PAL® Infiltration System is indicated 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

MicroAire PAL Infiltration System

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

10/13/2022

4. Device Identification

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

5. Legally Marketed Predicate Device(s)

Device name: Vitruvian Infiltration Pump
510(k) number: K170629
Manufacturer: Black & Black Surgical, Inc.

Device name: Liposuction Aspiration and Tumescent Infiltration Cannulae and Needles
510(k) number: K113795
Manufacturer: Black & Black Surgical

Device name: Single Spike 15' Large Bore Tubing
510(k) number: N/A – 510K exempt
Manufacturer: Black & Black Surgical

Reference Devices:

Device name: Wells Johnson Infusion System, Mode 20-6000-00
510(k) number: K991437
Manufacturer: Wells Johnson Co.

Device name: PAL System
510(k) number: K212024
Manufacturer: MicroAire Surgical Instruments, LLC

Device name: PAL Single-Use Cannulas
510(k) number: K192694
Manufacturer: MicroAire Surgical Instruments, LLC

Device name: PAL Multi-Use Cannulas and PAL Manual Wand
510(k) number: K171286
Manufacturer: MicroAire Surgical Instruments, LLC

Device name: MicroAire LipoFilter System
510(k) number: BK220674
Manufacturer: MicroAire Surgical Instruments, LLC

Device name: INEX Lipoplasty/Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles
510(k) number: K132353
Manufacturer: INEX

6. Indications for Use Statement

The PAL® Infiltration System is indicated for the purpose of aesthetic body contouring.

7. Device Description

The MicroAire® Power Assisted Liposuction (PAL®) Infiltration System is a medical device intended for aesthetic body contouring. The PAL Infiltration System is a stand-alone peristaltic Infiltration Pump, with the ability to control ON/OFF function to the PAL Handpiece (sold separately), the Infiltration Pump, or a Foot Switch (INF-FOOT-1) depending on the doctor's preference.

The PAL® Infiltration System is comprised of the following components that are subject to this 510K:

- INF-PUMP PAL Infiltration Pump
- Accessories
    - o PAL-INF-1600 Infiltration Tubing
    - o PAL-INF-XXXXX Single-Use Infiltration Cannulas
    - o PAL-INF-RXXXXX Multi-Use Infiltration Cannula
    - o INF-CBL-5020, Infiltration Pump to 5020 Console Connector Cable
    - o INF-FOOT-1, Infiltration Foot Switch

8. Substantial Equivalence Discussion

The following table compares the subject device to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The minor differences in the subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics for Pump

Attribute	**SUBJECT DEVICE**	**PREDICATE DEVICE / 510(k) HOLDER**	**Comparison**
510(k) Number	K220318	K170629	N/A
Product Code	QPB	QPB	N/A
Regulation Number	878.5040	878.5040	N/A
Indications For Use	The PAL® Infiltration System is indicated for the purpose of aesthetic body contouring.	The Vitruvian Infiltration Pump is intended to be used for: Aesthetic Body Contouring	Same
Mechanism of Operation			
Pump type	Peristaltic	Peristaltic	Same
Maximum flow rate	630 mL/min – with HK Surgical ITS-10 tubing 1300 mL/min – with MicroAire PAL Infiltration Tubing PAL-INF-1600	475 mL/min* 999 mL/min**	Different; The flow rate is determined by the peristaltic pump geometry and speed as well as the inner diameter of the section of tubing which is placed inside of the pump. Lower flow rates can be achieved using the Subject Device if a smaller diameter tubing is connected.

Attribute	SUBJECT DEVICE	PREDICATE DEVICE / 510(k) HOLDER	Comparison
			Higher flow rates can be achieved using the Subject Device if a larger diameter tubing is connected.
Housing/Materials	Steel	ABS Plastic	Different; Tumescent Infiltration pumps are non-patient contacting devices. They are utilized and maintained outside of the sterile field. Although the housing materials are different, this has no impact on the performance or the Intended Use of the pump.
Footswitch	Electric	Air powered	Different; Both footswitches activate the rotation of the pump. The difference between air powered and electric activation does not change the footswitch interaction with the device or how user interfaces with the footswitches during its use.
Pressure control	Knob to control RPM	Knob to control RPM	Same
Display	LED	LED	Same
Complies with ISO 10993-1	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Same

Table 5B – Comparison of Flow Rate against Reference Device

Attribute	Predicate Device #1	Subject Device:	Reference Device	Comparison
Device Name	Vitruvian Infiltration Pump	PAL Infiltration System	Wells Johnson Infusion System, 20-6000-00	N/A
Device Manufacturer	Black & Black Surgical, Inc.	MicroAire Surgical Instruments, LLC	Wells Johnson	N/A
510(k) Reference	K170629	K220318	K991437	N/A
Maximum flow rate	475 mL/min* 999 mL/min**	630 mL/min – with HK Surgical ITS-10 tubing 1200 mL/min – with MicroAire PAL Infiltration Tubing PAL-INF-1600	Maximum flow rate 1300mL/min (per IFU)	Similar; The flow rate is determined by the peristaltic pump geometry and speed as well as the inner diameter of the section of tubing which is placed inside of the pump. Lower flow rates can be achieved using the Subject Device if a smaller diameter tubing is connected. Higher flow rates can be achieved using the Subject Device if a larger diameter tubing is connected.

Table 5C – Comparison of Characteristics: Infiltration Single-Use and Multi-Use Cannulas

Attribute	Predicate Device #2 – Black & Black Surgical Multi-Use	Subject Device – PAL Infiltration Single-Use	Subject Device – PAL Infiltration Multi-Use	Comparison
Device Name	Liposuction Aspiration and Tumescent Infiltration Cannulae and Needles	PAL Infiltration Single Use Cannulas	PAL Infiltration Multi-Use Cannulas	N/A
Device Manufacturer	Black & Black Surgical	MicroAire Surgical, LLC	MicroAire Surgical, LLC	N/A

Attribute	Predicate Device #2 – Black & Black Surgical Multi-Use	Subject Device – PAL Infiltration Single-Use	Subject Device – PAL Infiltration Multi-Use	Comparison
510(k) Reference	K113795	K220318	K220318	N/A
FDA Product Code	QPB	QPB	QPB	Same
FDA Classification Name	System, suction lipoplasty for removal	System, suction lipoplasty for removal	System, suction lipoplasty for removal	Same
FDA Regulation Number	878.5040	878.5040	878.5040	Same
FDA Device Class	Class II	Class II	Class II	Same
Indications for Use	The aspiration and infusion cannulae and needles are indicated for aesthetic body contouring and general tissue aspiration.	The PAL® Infiltration System is indicated for the purpose of aesthetic body contouring.	The PAL® Infiltration System is indicated for the purpose of aesthetic body contouring.	Similar
Design	Cannula tube; Cannula tip; Cannula hub	Cannula tube; Blunt tip; Cannula hub	Cannula tube; Blunt tip; Cannula hub	Same
Fenestration	Multi-hole: Hole Size - 1mm Number of holes - 7 Hole Pattern - Wrap around in a spiral formation.	Multi-hole: Hole Size - 1.9mm Number of Holes - 22 Hole Pattern - Straight Formation 11 thru holes 90 degrees apart	Multi-hole: Hole Size - 1.9mm Number of Holes - 22 Hole Pattern - Straight Formation 11 thru holes 90 degrees apart	Different
	Basket: Three holes equally spaced radially with remaining material flared.	Flared Mercedes: Three holes equally spaced radially with remaining material flared.	Flared Mercedes: Three holes equally spaced radially with remaining material flared.	Same
Length	Available in 15cm, 26cm, 32cm, and 40cm lengths.	Available in 15cm, 22cm, and 30cm lengths.	Available in 15cm, 22cm, 30cm and 40cm lengths.	Similar

Attribute	Predicate Device #2 – Black & Black Surgical Multi-Use	Subject Device – PAL Infiltration Single-Use	Subject Device – PAL Infiltration Multi-Use	Comparison
		Note: No 40 cm length.		
Diameter	Available in 3.2mm (10 Gauge), 4mm, 5mm diameters	Available in 3mm, 4mm and 5mm diameters	Available in 3mm, 4mm and 5mm diameters	Similar
Style	Straight	Straight	Straight	Same
Materials	**Cannula Tube** – Stainless Steel **Cannula Hub** – Stainless Steel and Aluminum	**Cannula Tube** – Stainless Steel **Cannula Hub** Lexan HPS1R (polycarbonate) and Dupont Zytel ST801 (nylon)	**Cannula Tube** – Stainless Steel **Cannula Hub** –Vectra MT1310 (LCP) and Dupont Zytel ST801 (nylon) and a Dowel Pin made of 410 or 416 Stainless Steel	Cannula Tube – Same Cannula Hub – Different
Function	Black and Black Surgical Cannulae and Needles are used to remove fluid, soft tissue, and exudates and for infusion, utilizing a hollow stainless-steel tube and multiple tips, handle and attachment connectors that are in reusable and disposable configuration.	The Cannula steel tube is used to provide length and strength. The Cannula Tip is used to provide infiltration through eyelets (holes) in the tip. The hub is used to connect to the handpiece and tubing	The Cannula steel tube is used to provide length and strength. The Cannula Tip is used to provide infiltration through eyelets (holes) in the tip. The hub is used to connect to the handpiece and tubing	Similar
Sterile	Supplied non-sterile; Steam Sterilized by end user	Supplied sterile, Gamma sterilization	Supplied non-sterile; Steam Sterilized by end user	Different
Single-Use	No	Yes	No	Different
Complies with ISO 10993	Yes	Yes	Yes	Same

Table 5D – Comparison of Characteristics: Infiltration Tubing

Attribute	Predicate Device #3: Black & Black Single Spike 15' Large Bore Tubing	Subject Device: PAL Infiltration Tubing, K220318	Comparison
Device Name	Single Spike 15' Large Bore Tubing	PAL Infiltration Tubing	N/A
Device Manufacturer	Black & Black	MicroAire Surgical, LLC	N/A
510(k) Reference	N/A	K220318	N/A
FDA Product Code	GAZ	QPB	Different
FDA Classification Name	Tubing, Noninvasive	Suction Lipoplasty System	Different
FDA Regulation Number	880.6740	878.5040	Different
FDA Device Class	Class II	Class II	Same
Indications for Use	The suction and irrigation tubes are intended for instillation or aspiration of fluid to/from a targeted area of the body during liposuction procedures.	The PAL® Infiltration System is indicated for the purpose of aesthetic body contouring.	Similar
Design Characteristics	Available in one length ~15 feet	Available in one length ~16feet	Similar
Design	3-piece tubing construction; one peristaltic section, two length sections Single bag spike luer connection	3-piece tubing construction; one peristaltic section, two length sections Single bag spike No luer connection	Similar
Materials	Peristaltic section - Silicone	Peristaltic Section – PVC Length Section – PVC Bag Spike - ABS Tubing Connectors - PC	Different
Function	The peristaltic section interfaces with a peristaltic pump to provide fluid flow. The length sections of the tubing provide connections for the bag spike, tubing connectors, and luer connector.	The peristaltic section interfaces with a peristaltic pump to provide fluid flow. The length sections of the tubing provide connections for the bag spike, tubing connectors, and MicroAire infiltration cannula.	Similar

Attribute	**Predicate Device #3: Black & Black Single Spike 15' Large Bore Tubing**	**Subject Device: PAL Infiltration Tubing, K220318**	**Comparison**
Sterile	Supplied Sterile (Gamma Irradiation)	Supplied sterile (EtO)	Similar
Single-Use	Yes	Yes	Same
Complies with ISO 10993	Yes	Yes	Same

Table 5E – Comparison of Single-Use Data against Reference Device

Attribute	**Reference Device: INEX Lipoplasty/Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles**	**Subject Device: MicroAire PAL Infiltration Single-Use Cannula**	**Comparison**
Device Name	Lipoplasty/Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles	MicroAire PAL Infiltration Single-Use Cannula	N/A
Device Manufacturer	INEX	MicroAire Surgical, LLC	N/A
510(k) Reference	K132353	K220318	N/A
Single-Use	Yes	Yes	Same
Supplied Sterile	Yes	Yes	Same

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of MicroAire PAL Infiltration System and to show substantial equivalence to the predicate device, MicroAire completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The PAL Infiltration System passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5 – Passed
- Sensitization and Irritation testing per ISO 10993-10 – Passed
- Irritation testing per ISO 10993-10 – Passed
- Pyrogenicity per USP <151> - Passed
- Acute Systemic Toxicity per ISO 10993-11 - Passed
- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – Passed
- Infiltration Pump Flow Rate - –meets internal specifications

- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained

10. Statement of Substantial Equivalence

Based on the information provided in this submission, it is concluded that the MicroAire PAL Infiltration System has the same indications for use as the Vitruvian Infiltration System. Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, MicroAire PAL Infiltration System has been determined to be substantially equivalent to Vitruvian Infiltration Pump.