6/21/2022

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

Re: K212024
Trade/Device Name: PAL System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Glenn Gerstenfeld:

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 June 10, 2022. Specifically, FDA is updating this SE Letter to update the correct product code from MUU to QPB as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Deborah Fellhauer, OHT4: Office of Surgical and Infection Control Devices, 301-796-9570, Deborah.Fellhauer@FDA.HHS.GOV.

Sincerely,

Deborah A. Fellhauer -S

Digitally signed by Deborah A. Fellhauer -S

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

June 10, 2022

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

Re: K212024
Trade/Device Name: PAL System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: March 11, 2022
Received: March 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 A. Fellhauer -S

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

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)*

K212024

Device Name
MicroAire® PAL® System

Indications for Use *(Describe)*
For 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

PAL® System

K212024

1. Submission Sponsor

MicroAire® Surgical Instruments, LLC

3590 Grand Forks Blvd

Charlottesville

VA, 22911

USA

Contact: Glenn Gerstenfeld

Title: Vice President, QA/RA and Compliance Officer

2. Date Prepared

23 June 2021

3. Device Identification

Trade/Proprietary Name:	PAL® System
Common/Usual Name:	Suction Lipoplasty System
Classification Name:	System, Suction, Lipoplasty For Removal
Regulation Number:	878.5040
Product Code:	QPB
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

4. Predicate Device(s)

Device name: Vibrasat® Power (console and vibration handpiece for the liposuction cannula)

510(k) number: K053451

Manufacturer: Moeller Medical GMBH & Co. KG.

The device of interest for comparison are the Vibrasat® power console and handpiece. These two devices are controlled by the user during Lipoplasty procedures, the console for settings and the handpiece for the manipulation of the cannula for the fat removal. The predicate device and subject device are detailed further for comparison in Section 12 – Substantial Equivalence.

Reference Predicate

Device name: MicroAire "Power Aspiration Device" PAD System

510(k) number: K973268

Manufacturer: MicroAire® Surgical Instruments, LLC

The *MicroAire Power Aspiration Device (PAD) System is the original PAL System without the enhanced features*. The reference device and subject device are detailed further Section 12 – Substantial Equivalence, though the reference device is only used in the historical context. The predicate serves as the substantial equivalence.

5. Intended Use / Indication for Use Statement

For aesthetic body contouring

6. Device Description

The MicroAire® Power Assisted Liposuction (PAL) System is a medical device intended to be used for the aspiration of autologous adipose tissue in lipoplasty procedures. The PAL system consists of three components: electric instrument console, handpiece, and cable. The PAL-650 handpiece is powered by the MicroAire 5020 Electric Instrument Control console via the 5006 PAL cable and connected to an independent aspiration source. The PAL-650 handpiece reciprocates a cannula used in liposuction procedures for aspiration of fat tissue. For more details on device see Section 11 – Device Description.

7. Substantial Equivalence Discussion

The following table compares the PAL® System to the predicate device 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 of PAL® 5020 Console to Vibrasat® Power Console

	COMPANY **MicroAire® Surgical Instruments**	**PREDICATE** **Moeller Medical GmbH & Co. KG**	**Device Comparison**
Trade Name	**PAL® System** • **5020 Console**	**Vibrasat® Power** • **Console**	
510(k) Number	K212024	K053451	N/A
Classification			

	COMPANY MicroAire® Surgical Instruments	PREDICATE Moeller Medical GmbH & Co. KG	Device Comparison
Trade Name	**PAL® System** • **5020 Console**	**Vibrasat® Power** • **Console**	
Image			N/A
Product Code	QPB	QPB	Same
Regulation Number	21 CFR 878.5040 Class II	21 CFR 878.5040 Class II	Same
Regulation Name	Suction Lipoplasty System	Suction Lipoplasty System	Same
Indications for Use	For aesthetic body contouring	Aesthetic body contouring	Same
Device Overview			
User	Only trained and experienced healthcare providers/professionals should use this medical equipment.	Doctors who can demonstrate that they have the necessary expertise through the relevant specialist training or approved, specialist further training.	Similar to subject device
Mechanism of Action	MicroAire power assisted liposuction is an electronic control system designed to reciprocate a cannula in lipoplasty applications.	Vibration liposuction is a tried-and-tested method for fat removal. With this method, the suction cannula is vibrated axially which, in combination with the suction vacuum, cuts and removes the fatty tissue microscopically and gently.	Same
Display	The color touch screen display provides an intuitive graphical user interface that allows users to view system status and set parameters with a touch of the screen.	LED stroke rate display with tactile control buttons for stop/start, increase/decrease rate and rate set.	Similar
Speed Control	• Touch screen • Handpiece	• Console tactile buttons • Foot pedal	Similar
Physical Characteristics			

	COMPANY MicroAire® Surgical Instruments	PREDICATE Moeller Medical GmbH & Co. KG	Device Comparison
Trade Name	**PAL® System** • **5020 Console**	**Vibrasat® Power** • **Console**	
Dimensions	304.8 mm x 355.6 mm x 152.4 mm	150 mm x 100 mm x 200 mm	Different.
Weight	6.35 kg	2.8 kg	Different
Display	Color touchscreen display	Led display illumination	Different
AC Powered	100 VAC – 240 VAC, 50/60 Hz	100 VAC – 240 VAC, 50/60 Hz	Same
Number of Attachable Devices	Two (2) Handpieces	One (1) Handpiece One (1) Footswitches	Different
Safety and Performance			
Electrical Safety Testing Passed	IEC/EN 60601-1-2:2014 IEC 60601-1:2005 IEC 60601-1-6:2013 IEC 62366: 2015	IEC/EN 60601-1-2:2007 IEC 60601-1:2005 IEC 60601-1-6:2010 IEC 62366: 2007	Similar
Performance	4000 – 5000 strokes/min.	3000 – 5000 strokes/min.	Similar
Reuse			
Cleaning / disinfecting	Validated germicidal wipe down method in IFU	Validated alcohol wipe down method in IFU	Similar
Operating Environment			
Environment: **Temperature** **Humidity**	Operation conditions 15°C to +24°C 20%-60%	Operation conditions +10°C to +25°C 30 to 75%	Similar

Table 5B – Comparison of Characteristics of PAL-650 Handpiece to Vibrasat® Handpiece

	COMPANY MicroAire® Surgical Instruments	PREDICATE Moeller Medical GmbH & Co. KG	Device Comparison
Trade Name	**PAL-650 Handpiece and 5006-PAL Cable**	**Vibrasat® Power Handpiece w/Cable**	
510(k) Number	K212024	K053451	N/A
Device Overview			
Image			N/A

	COMPANY MicroAire® Surgical Instruments	PREDICATE Moeller Medical GmbH & Co. KG	Device Comparison
Trade Name	**PAL-650 Handpiece and 5006-PAL Cable**	**Vibrasat® Power Handpiece w/Cable**	
Mechanism of Action	The PAL-650 is a powered surgical instrument that reciprocates a cannula used in liposuction procedures.	The *Vibrasat® power* transfers very rapid vibrations in an axial direction to a cannula connected to the handle and thus supports the user's hand movements.	Same
User	Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.	Doctors who can demonstrate that they have the necessary expertise through the relevant specialist training or approved, specialist further training.	Similar. The scope of PAL System includes professionals also involved in the operating procedure.
Technology Overview	The reciprocating output shaft of the handpiece drives the cannula through a stroke distance of 2.8 mm (±0.4 mm) at a rate of 4,000 to 5,000 strokes/minute.	Axial vibration liposuction power through 3,000 to 5,000 strokes/min with a stroke of 2.8 mm	Similar. Predicate device has a lower threshold stroke rate.
Physical Characteristics			
Dimensions	25 mm x 38 mm x 250 mm (width x thickness x length) [45.5 mm x 250 mm ~ equivalent diameter x length envelope]	55 mm x 180 mm (diameter x length)	Similar
Weight	0.5 kg (Handpiece) 0.28 kg (Cable)	0.75 kg (handpiece and cable)	Similar. The weight difference is insignificant to the overall weight.
Power source	Console, detachable cable.	Console, detachable cable	Same
Performance			

	COMPANY MicroAire® Surgical Instruments	PREDICATE Moeller Medical GmbH & Co. KG	Device Comparison
Trade Name	**PAL-650 Handpiece and 5006-PAL Cable**	**Vibrasat® Power Handpiece w/Cable**	
Duty Cycle	Duty cycle of 2 hours continuous use/ 2 hours off.	30-minutes cycle with a subsequent break of 60 minutes. This cycle may be repeated as often as necessary.	Different
Surface Temperature during Operation	<41°C	<43°C	Similar. Subject device is slightly cooler at the maximum temperature
Reuse			
Cleaning	• Manual • Automated	• Manual • Automated	Similar • For manual cleaning, predicate process is ≤40°C for soak and rinse while subject's process is ≥49°C. • For automated cleaning, the predicate has a 7-step process with a neutralizing solution while the subject's process is 6 steps not requiring neutralizing. Temperatures are similar to equal across process.
Sterilization	Handpiece and cable are Autoclavable by end user, steam sterilization	Handpiece and cable are Autoclavable by end user, steam sterilization	Same. Both callout Dynamic-Air- Removal steam method. Subject's process also allows for gravity displacement steam method.

8. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the PAL® System and to show substantial equivalence to the predicate device, MicroAire® Surgical Instruments completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The

PAL® 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.

- Biological evaluation per ISO 10993-1 – The 5006-PAL Instrument cable was considered biocompatible for the intended use. For more details see Section 15 – Biocompatibility.
- Electrical safety testing per IEC 60601-1 – The PAL System was tested for electrical safety per the standard, details for testing are in Section 18 – Non-clinical Bench Testing.
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – The PAL System underwent interference testing, details for testing are in Section 17 – Electromagnetic Compatibility.
- Software verification and validation per IEC 62304/FDA Guidance – results /conclusion are detailed in Section 16 – Software.
- Mechanical Tensile Testing, results /conclusion are detailed in Section 18 – Non-clinical Bench Testing.
- Sterilization validation – The Handpiece and Cable demonstrates SAL of $10^{-6.}$, for details of testing see Section 14 – Sterilization and Shelf life.
- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained. Details for testing are in Section 18 – Non-clinical Bench Testing.

9. 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.

10. Statement of Substantial Equivalence

The PAL® System, the subject device, has the same intended use and similar technological characteristics that has been compared and contrasted with the chosen predicate device, and that the subject does not raise additional questions regarding its safety and effectiveness. Clinical and non-clinical testing has demonstrated the PAL® System is as safe and effective as the predicate device. Therefore, through intended use, technology, and performance testing, the PAL® System is substantially equivalent to the predicate device.