06/08/2026

Lipocosm, LLC
Ercan Dilsen
VP Operations
580 Crandon Blvd. Suite 201
Key Biscayne, Florida 33149

Re: K251944
Trade/Device Name: Lipocosm Harmonic System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: QPB
Dated: January 30, 2026
Received: January 30, 2026

Dear Ercan Dilsen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 -S

Digitally signed by Alicia Hemphill -S
Date: 2026.06.08 19:31:04 -05'00'

Alicia L. Hemphill (Johnson), MS
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251944

Please provide the device trade name(s).

Lipocosm Harmonic System

Please provide your Indications for Use below.

Lipocosm Harmonic System is intended for aesthetic body contouring.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

Lipocosm Harmonic System

1. **Submission Sponsor**

Lipocosm LLC
580 Crandon Blvd, #201
Key Biscayne, FL, 33149 USA
Contact: Ercan Dilsen, Vice President Operations

2. **Date Prepared**

April 7, 2026

3. **Device Identification**

Trade/Proprietary Name:	Lipocosm Harmonic System
Common/Usual Name:	Suction Lipoplasty System
Classification Name:	System, Suction, Lipoplasty for Removal without the Return of Adipose Tissue
Regulation Number:	21 CFR 878.5040
Product Code:	QBP
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

4. **Predicate Device(s)**

Device name: MicroAire® PAL® System (Console and vibration handpiece for the liposuction cannula)

510(k) number: K212024

Manufacturer: MicroAire® Surgical Instruments, LLC

The device of interest for comparison is the MicroAire® PAL® Console and Handpiece of the currently marketed and predicate MicroAire PAL® System. 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 7 – Substantial Equivalence.

5. Intended Use / Indication for Use Statement

Lipocosm Harmonic System is intended for the removal of tissue and fluid from the body during general surgical procedures, when used with commercially available aspiration device, including suction lipoplasty for the purpose of aesthetic body contouring.

6. Device Description

The main components of the Subject Lipocosm Harmonic System as follows:

- A reuseable Handpiece that oscillates the Cannula in two dimensions in a plane perpendicular to its axis to facilitate lipoaspiration.
- A Control Box that controls the frequency of Cannula displacement.
- A reusable 3mm Cannula has a plastic hub proximally for attachment to the reuseable Handpiece and employs a port on its proximal end for connecting it with the standard vacuum (suction) tubing. The distal end of the Cannula employs 12 holes that are used for the suction.

  The oscillation of the Cannula is intended to help increase flowrate adipose tissue.
- A Foot Pedal that starts and stops the movement of the Cannula employs a cable that connects the Foot Pedal to the Control Box.
- A reusable Handpiece Cable that connects the control box to the Handpiece.
- A Power Supply for connecting the Control Box to an electric outlet.

7. Substantial Equivalence Discussion

The following table compares the Lipocosm Harmonic System to the currently marketed and predicate MicroAire® PAL System (K212024) with respect to indications for use, principles of operation, technological characteristics, The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

Tables 1 and 2, respectively provides a summary comparison between the Subject Control Box and the Handpiece of the Lipocosm Harmonic System and the currently marketed and predicate MicroAire® PAL System.

Table 1 **Device Comparison Table**			
	Subject Device	**Predicate Device**	**Device Comparison**
510(k) Number	K251944	K212024	NA
Applicant	Lipocosm, LLC	MicroAire Surgical Instruments, LLC	NA
Address	580 Crandon Blvd. Suite 201, Key Biscayne FL 33149	3590 Grand Forks Road, Charlottesville, VA 22911	NA
Device Name	Lipocosm Harmonic System (LHS)	PAL System	NA
Classification Regulation, Class	21 CFR 878.5040, Class II	Identical	Same
Product Code	QPB	Identical	Same
Indications for Use	For aesthetic body contouring	For aesthetic body contouring	Same
Cannula	Material: Fabricated from medical Grade 304 Stainless Steel, and aluminum luer type connector. No. of apertures: 12 Length: 35cm Diameter: 3mm	PAL System Del Vecchi 12 Track Cannula: Material: Fabricated from medical-grade 304 stainless steel with a straight port connector. No. of apertures: 12 Length: 22 / 30cm Diameter: 3 / 4mm	Similar. Non-clinical testing was performed to address differences in cannula length.

Device Overview Control Box			
Device Description	LHS is intended for the removal of tissue and fluid from the body during lipoplasty procedures, when used with commercially available aspiration devices, including suction lipoplasty for the purpose of aesthetic body contouring. The LHS consists of four main components: Electric instruments: Control Box, Hand Piece, Cable and Foot Pedal. The LHS Handpiece oscillates the LHS Cannula in liposuction procedures in two dimensions for aspiration of fat tissues. Note, LHS is connected to an independent aspiration source	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.	Similar. Subject and predicate devices include emulsification/fragmentation of tissue with differing mechanism of action.
Image			Similar with regards to functionality.
User	Only trained and experienced healthcare providers/professionals should use this medical equipment	Identical	Same
Mechanism of Action	The electronic Control Box of the Lipocosm Harmonic System that oscillates the Cannula in two dimensions in a plane perpendicular to its axis to facilitate lipoaspiration in lipoplasty applications.	MicroAire® Console is an electronic control system designed to reciprocate the cannula back and forth along the same path to facilitate lipoaspirate in lipoplasty applications.	Different, however, the mechanism of action of the subject and predicate devices facilitate lipoaspiration by emulsification/fragmentation of tissue.

Motion	The cannula of LHS oscillates in two dimensions – side to side, perpendicular to the axis of the cannula. Oscillation refers to vibrating motion around a central point along the plane perpendicular to the axis of the cannula.	The cannula of the PAL System reciprocates both forward and backward, parallel to the axis of the cannula, and side to side, perpendicular to the axis of the cannula. Reciprocation is a straight-line back-and-forth motion along the same path.	Different. Non-clinical testing was performed to assess the equivalence of the fragmentation/emulsification of the subject device oscillating motion compared with the predicate device reciprocating motion.
Display	The LHS has a panel with an on/off switch, a potentiometer to control the frequency of the cannula, a receptacle to connect the Handpiece Cable, a receptacle that connects the Cable of the Foot Pedal, and a receptacle that connects to the power supply.	The color touch screen display of the Console provides an intuitive graphical user interface that allows users to view system status and set parameters with a touch of the screen. It also includes receptacle to connect the Cable and a receptacle that connects the control system to the power outlet	Different. The display of the two systems is different, however both systems provide the same functionality.
Speed Control	Potentiometer	Touch screen	Different. The speed controls of the two systems are different, however both systems provide the same functionality.
Sterility	Non-sterile	Identical	Same
Weight	0.632 Kg	6.35Kg	Different, however the intended purpose is the same.
AC Powered	100 VAC – 240 VAC, 50/60 Hz	Identical	Same

No. of Attachable Devices	One (1) Handpiece One (1) Foot Pedal	Two (2) Handpieces	Similar, both devices utilize Handpiece.
Safety and Performance			
Electrical Safety Testing Passed	IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 for use in conjunction with IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020, and IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 IEC 60601-1-2 ed 4.1 (2020-09)	IEC 60601-1:2005 IEC 60601-1-6:2013 IEC 62366: 2015 IEC/EN 60601-1-2:2014	Same
Performance	0-4000 oscillations/min.	4000 – 5000 strokes/min.	Similar, since intended purpose is the same
Operating Environment			
Environment: Temperature Humidity	Operation conditions 15°C to +24°C 20%-60%	Identical	Same

Table 2
Handpiece Comparison Table

	Subject Device	**Predicate Device**	**Device Comparison**
Image			NA
Mechanism of Action	The Handpiece of the **LHS** utilizes an eccentric mass in the Handpiece that oscillates the Cannula in two-dimensional plane perpendicular to the Handle in the liposuction procedure	The MicroAire® PAL Handpiece is a powered surgical instrument that reciprocates a cannula back and forth in the liposuction procedure.	The Mechanism of Actions of the two systems are different, however the displacement and frequency of the Cannula of the two devices are similar.

Table 2 **Handpiece Comparison Table**			
	Subject Device	**Predicate Device**	**Device Comparison**
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	Identical	Substantially Equivalent
Technology	The power assisted Cannula oscillation ranges from 0 to 4,000 oscillations/minute in two dimensions. The oscillation of the Cannula is approximately 3.5mm in the long axis.	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.	Different, however, the function of the subject and predicate devices facilitate lipoaspiration by emulsification/fragmentation of tissue.
Dimension	38mm x 40 mm x 248 mm (width x thickness x length). The section that is held in operators' hand is 30mm x 38 mm (width x thickness)	25 mm x 38 mm x 250 mm (width x thickness x length) [45.5 mm x 250 mm ~ equivalent diameter x length envelope]	Similar.
Weight	0.58 kg (Handpiece) 0.26 kg (Cable)	0.5 kg (Handpiece) 0.28 kg (Cable)	Similar.
Power Source	Control Box, detachable cable	Identical	Same
Performance			
Duty Cycle	Duty cycle of 30 minutes continuous use, 2 hours off	Duty cycle of 2 hours continuous use, 2 hours off	Different, however, the use of the subject device, to facilitate lipoplasty, is ~25-30 minutes non-continuous.

Table 2 **Handpiece Comparison Table**			
	Subject Device	**Predicate Device**	**Device Comparison**
Surface Temperature during Operation	< 30°C	< 41°C	Similar
Reuse			
Cleaning	Manual	• Manual • Automated	Same
Sterilization	Handpiece and Handpiece Cable are steam sterilized by the end user	Identical	Same

8. Non-Clinical Performance Data

To demonstrate substantial equivalence of the LHS to the currently marketed and predicate, MicroAire® PAL® System, Lipocosm LLC completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The LHS passed the tests in accordance with internal requirements, national standards, and international standards provided below, supporting its substantial equivalence to the currently marketed and predicate MicroAire® PAL® System.

- Biological evaluation per ISO 10993-1 – The results of the testing demonstrate that the Cannula was biocompatible.
- Medical electrical equipment per IEC 60601-1:2005/AMD 2:2020, AAMI ES60601-1:2005/AMD2:2021, EN 60601-1:2006/A2:2021 entitled, "*Part 1: General requirements for basic safety and essential performance.*" The results of this test demonstrate the basic safety of the LHS.
- Medical electrical equipment per IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 for use in conjunction with IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020, and IEC 60601- 1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601- 1:2005/AMD2: 2020 entitled, "*General requirements for basic safety and essential performance - Collateral standard: Usability*." The results of this test demonstrate the electromagnetic compatibility of the LHS.
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 ed 4.1 (2020-09) entitled, "*Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.*" The results of this test demonstrate the basic safety of the LHS.

- Bench / Design Validation testing was performed on the LHS. Test results demonstrate that the LHS met the acceptance criteria and perform as intended.
- Cleaning validation study was performed by MycoScience on the reusable components of the Subject LHS using the manual cleaning procedure specified in the Instruction for Use of the Subject Lipocosm Harmonic System. The cleaning validation demonstrates that the cleaning method is adequate.
- Sterilization validation – The results of the sterilization validation of the reuseable components of the LHS; Cannula, Handpiece, and Handpiece Cable demonstrate that a SAL of 10^{-6} is achieved when these reusable components are Steam sterilization pre-vacuum cycle of 4 minutes at 270^{0}F.

9. Clinical Performance Data

There was no human clinical testing required to support the substantial equivalence of the LHS as the indications for use is equivalent to the currently marketed and predicate device. These types of devices, including the predicate devices, have been on the market for many years.

10. Statement of Substantial Equivalence

The subject device, the LHS, has been compared with the currently marketed and predicate device, MicroAire® PAL® System. Through intended use, technology, and performance testing, the LHS is substantially equivalent to the currently marketed and predicate MicroAire® PAL® System.