



November 27, 2024

Cellmyx
Jacqueline Schmainda
Regulatory Consultant
6352 Corte Del Abeto
Suite A
Carlsbad, California 92011

Re: K241835

Trade/Device Name: AirSculpt Body Contouring System (AIRS-1-SYS)
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: QPB
Dated: October 30, 2024
Received: October 30, 2024

Dear Jacqueline Schmainda:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2024.11.27 16:23:04 -06'00'

Alicia Hemphill
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K241835

Device Name

AirSculpt Body Contouring System (AIRS-1-SYS)

Indications for Use (Describe)

The AirSculpt Body Contouring System is indicated for the removal of tissue or fluid from the body during general liposuction procedures 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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Cellmyx
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Correspondent Address	null United States
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Correspondent Contact	Ms. Jacqueline Schmainda
Correspondent Contact Email	jaschmainda@gmail.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	AirSculpt Body Contouring System (AIRS-1-SYS)
Common Name	Suction lipoplasty system
Classification Name	System, Suction, Lipoplasty For Removal
Regulation Number	878.5040
Product Code(s)	QPB

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K010311	Lipomatic; Lipomatic Liposuction Device	QPB

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The AirSculpt System is a surgical device designed for the removal of subcutaneous adipose tissue during liposuction procedures performed for cosmetic purposes. The AirSculpt System includes components necessary for the vacuum-suction removal of excess adipose tissue from the body, including a handpiece that accommodates the interchangeability of lipoplasty cannulae, a console for centralized control of the system, tubing to facilitate aspiration of subcutaneous adipose tissue, and a foot pedal for operation. Other elements necessary for the use of the AirSculpt System include commonly used Class I and Class II surgical devices such as lipoplasty cannula that are introduced into the patient and swept over subcutaneous adipose tissue for suction removal and a suction canister into which aspirated adipose tissue is collected. An optional use Instrument Sleeve accessory is also available for use with the AirSculpt Handpiece and its use is based purely on physician preference.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The AirSculpt Body Contouring System is indicated for the removal of tissue or fluid from the body during general liposuction procedures for the purpose of aesthetic body contouring.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of the subject and predicate devices are the same.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Performance Data

The AirSculpt Body Contouring System has undergone bench testing and third-party testing with passing results:

Bench testing

IEC 60601-1 Edition 3.2 2020-08

IEC 60601-1-2 Edition 4.1 2020-09

Cleaning and reprocessing validation

AirSculpt Triple Port Tubing:

ANSI AMMI ISO 11137-1:2006/(R)2015

ISTA 3A

ASTM F88

ASTM F2096-11

Clinical Data

Clinical data was not required to support the substantial equivalence of the AirSculpt Body Contouring System to the predicate device.

Conclusion

The AirSculpt Body Contouring System is substantially equivalent to the predicate device and any differences do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Bench testing included visual and inspection testing that included performance testing, shelf-life testing, functional testing (connector, operation, indicators, and pneumatic safety). Testing verified that the AirSculpt Body Contouring System conforms to specification.