U.S. FOOD & DRUG ADMINISTRATION

April 28, 2023

AuraGen Aesthetics, LLC
Attention: Randy J. Prebula
Hogan Lovells US, LLP
555 Thirteenth Street, NW
Washington, DC 20004
Email address: (b) (6) @hoganlovells.com

Re: BK220717 (Formally K190278)
Trade/Device Name: AuraGen 123 Suction Lipoplasty System (A123)
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Prebula:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative correction related to administrative letter dated February 9, 2023. Specifically, FDA is updating this administrative letter because the submission tracking number and point of contact in the header on the second page were stated incorrectly.

As stated in the administrative letter dated February 9, 2023, FDA updated your previous substantial equivalence (SE) determination letter dated May 3, 2019 because FDA assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

For more information, please refer to the Federal Register Notice *Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care To Produce a Therapeutic Article* (86 FR 50887, available at https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Hosna Keyvan by email at hosna.keyvan@fda.hhs.gov.

Sincerely,

Heather Lombardi, PhD
Acting Director
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Enclosure

May 3, 2019

AuraGen Aesthetics LLC
% Mr. Randy Prebula
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K190278
Trade/Device Name: AuraGen 123 Suction Lipoplasty System (A123)
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: February 8, 2019
Received: February 8, 2019

Dear Mr. Prebula:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For David Krause, Ph.D.
Acting Division Director
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*
K190278

Device Name

The AuraGen 123™ Suction Lipoplasty System (A123)

Indications for Use *(Describe)*

The A123 is used for aspiration, harvesting, filtering and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is to be used without any additional manipulation.

The A123 is intended for use in the following surgical specialties when aspiration of soft tissue is desired: plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

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.

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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

AuraGen Aesthetics' AuraGen 123™ Suction Lipoplasty System (A123)

Submitter
AuraGen Aesthetics LLC
11 Dellbrook Road, Weston, MA 02493

Phone: 617-818-4008
Facsimile: 857-999-3929
Contact Person: Yiannis Monovoukas, Ph.D.
Date Prepared: April 26, 2019

Name of Device: AuraGen 123™ Suction Lipoplasty System
Common or Usual Name: A123
Classification Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU (General and Plastic Surgery Panel)

Predicate Device

510(K) # K120902
Trade name: GID 700 Tissue Canister
Manufacturer: The GID Group, USA
(Distributed in the US as REVOLVE™ System by LifeCell Inc.)

Reference Device: N/A

Device Description

The A123 is a suction lipoplasty system designed to be used in the operating room in conjunction with, and attached to, a user-provided liposuction cannula, a vacuum source, and a waste canister. The A123 allows the surgeon to conveniently and accurately harvest, wash, filter, concentrate, and transfer autologous adipose tissue for reinjection into the same patient for body contouring in cosmetic and reconstructive surgery applications during the same procedure in which autologous adipose tissue is collected. The system is a sterile, disposable unit for single patient use.

The A123 consists of the following components:

- Collection chamber
- Collection mesh basket
- Concentration chamber with fluid-absorbing pads
- AuraClens™ powder packets
- Outlet tube and drain valve with tube clamp
- Mixing spatula

The A123 is to be used together with FDA-cleared devices (such as a lipoplasty device [Product Code MUU, Regulation Number 21 CFR 878.5040], liposuction cannula, high vacuum tubing, waste container, syringes [e.g. 60 cc Toomey-tip syringes, Luer-Lock, Product Code KYZ], and room-temperature, sterile 0.9% normal saline solution, all provided by the user.

Intended Use / Indications for Use

The A123 is used for aspiration, harvesting, filtering and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is to be used without any additional manipulation.

The A123 is intended for use in the following surgical specialties when aspiration of soft tissue is desired: plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

Performance Data

The Company conducted biocompatibility testing for the A123 and the AuraClens powder in accordance with the requirements of ISO 10993 for external communicating devices having contact < 24hours. In all instances, the test articles were found to be biocompatible.

The A123 and the AuraClens powder were sterilized by Gamma irradiation and both met the sterility requirements per ISO 11137 – *Sterilization of Health Care Products*.

In addition, the following table summarizes the bench testing performed with the device:

Bench Test	Methods
Cell Viability	Trypan Blue Dye Exclusion test
Fat Volume	Processed adipose tissue was centrifuged to separate the oil, fat, and aqueous phases. The volume of the fat layer was measured.
Fat Concentration	Processed adipose tissue was centrifuged to separate the oil, fat, and aqueous phases. The fat concentration was calculated as: volume of the fat layer/volume of adipose tissue processed.
Time-to-Graft (TTG)	Time from the start of the washing step to the end of the transfer/extraction step was measured.)
Device Usability	Usability of the device was evaluated.
Canister implosion	A123 units were tested for medical vacuum suction canister implosion test requirements per ISO 10079-1:2015(E) Medical Suction Equipment Part 1, Section 6.1.3 and Annex A.3
Tubing collapse	A123 units were tested for medical vacuum suction canister tubing collapse test requirements per ISO 10079-1:2015(E) Medical Suction Equipment Part 1, Section 6.3.1 and Annex A.4.
System leak	A123 units were tested for vacuum seal to determine leakage per the

Bench Test	Methods
	specification in ISO 10079-1:2015(E) Medical Suction Equipment Part 1, Section 7.7.1 and Annex A.8.1.
Tubing tensile strength (pull-off force) (to assess tubing connections)	A123 units were tested to measure the tensile strength (pull-off force) of the A123 tubing assembly and the user-supplied liposuction and aspiration tubing from the A123 tubing connectors.

The A123 meets the acceptance criteria for all tests.

Substantial Equivalence

The A123 is as safe and effective as the GID 700 Tissue Canister (the “Predicate Device”) that FDA has already cleared (K120902). The A123 has the same intended uses and indications for use, as well as similar technological characteristics and principles of operation as its predicate device. In addition, the minor technological differences between the A123 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the A123 is as safe and effective as the GID 700 Tissue Canister. Thus, the A123 is substantially equivalent.