Genesis Biosystems Inc.
Attention: Matt Eaton
1500 Eagle Court
Lewisville, TX 75057

February 9, 2023

Re: BK220714 (Formally K172714)
Trade/Device Name: LipiVage
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Eaton:

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 December 8, 2017. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

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, Julia Russell at 240-704-0618 or by email at Julia.Russell@fda.hhs.gov.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66 G609
Silver Spring, MD 20993 0002

December 8, 2017

Genesis Biosystems, Incorporated
% Mr. Stuart R. Goldman
Senior Consultant, Regulatory
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K172714
Trade/Device Name: LipiVage®
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: August 24, 2017
Received: September 8, 2017

Dear Mr. Goldman:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K172714

Device Name
LipiVage®

Indications for Use *(Describe)*

LipiVage® 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 only to be used without any additional manipulation.

LipiVage® 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.

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

LipiVage®

K 172714

5.1 Submission Sponsor

Genesis Biosystems, Inc.

1500 Eagle Court

Lewisville, TX 75057

Phone Number: 972.315.7888

Contact: Jim Lafferty

Email: JLafferty@genesisbiosystems.com>

5.2 Submission Correspondent

Emergo Global Consulting, LLC

2500 Bee Cave Road, Bldg. 1, Suite 300

Austin, TX 78746

Office Phone: 512.327.9997

Contact: Stuart R. Goldman, Senior Consultant, RA/QA

Email: project.management@emergogroup.com

5.3 Date Prepared

August 24, 2017

5.4 Device Identification

Trade/Proprietary Name: LipiVage®

Common/Usual Name: Harvesting syringe

Classification Name: Suction lipoplasty system

Regulation Number: MUU

Product Code: 878.5040

Device Class: Class II

Classification Panel: General & Plastic Surgery

5.5 Legally Marketed Predicate Device

GID 700™ (K120902)

5.6 Device Description

LipiVage® is a 60cc hollow barrel harvesting syringe with plunger and an in-line polyester filter that is intended to receive, concentrate and filter autologous adipose tissue from lipoplasty procedures, for re-implantation of the extracted tissue back into the same patient at other anatomical locations in their body using a piston syringe and injection cannula. At one end of the LipiVage® harvesting syringe there is a male connector (nozzle) for fitting the female connector (hub) of a cannula for the harvesting of fat cells, while at the other end of the device there is a universal tubing connection to attach to a tubing set (not supplied by Genesis) that is connected to a controlled vacuum source, such as an aspirator or wall suction in the user facility. The LipiVage® harvesting syringe incorporates an in-line filter so there is no need to centrifuge, decant or expose fat cells to unnecessary handling. The device is for professional use only, made from medical grade polymers, single use, and provided sterile to the user.

5.7 Indication for Use

LipiVage® 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 only to be used without any additional manipulation.

LipiVage® 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.

5.8 Substantial Equivalence Discussion

Genesis Biosystems has chosen the GID 700™ harvesting canister system as the predicate device for its LipiVage® harvesting syringe. The GID 700™ was cleared by the FDA under K120902. The following table compares the subject device to the predicate device with respect to their indications for use, technology and performance testing, thus demonstrating the basis for determination of substantial equivalence between these devices.

Table 5-1 – Device Comparison: LipiVage® vs. GID 700™

Regulatory Information			
Device Name	**LipiVage®**	**GID 700™**	**Similarities/Differences**
Manufacturer	Genesis Biosystems	Gid Group	NA
510(k)	Pending	K120902	NA

Product Code	MUU	MUU	Same
Regulation	§878.5040	§872.5040	Same
Class	II	II	Same
Indications for Use	LipiVage® 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 only to be used without any additional manipulation. The LipiVage® 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.	The GID 700™ 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 only to be used without any additional manipulation. The GID 700™ 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.	Same
Prescription use	Yes	Yes	Same
Fundamental Scientific Technology			
System Concept	Closed loop	Closed loop	Same
Source of Energy	User supplied vacuum.	User supplied vacuum.	Same
Device Size (fill volume)	Syringe: 60 cc	Canister: 700 ml	The differences in the size of the subject and pedicate devices are a function of their overall differences in design gemoteries (syringe vs. canasiter), and not considered to have any significant difference in the overall quality of the

			harvested fat.
Device Materials	Syringe: Molded, polycarbonate - Plunger Tip: Polyolefin - O-Rings: Silicone	Canister: Polymer (unknown)	The subject and predicate device are made of similar medical grade polymer materials.
Device Filter	 Estene® Polyester thread (natural color) woven filter fabric with a calculated mesh opening of 180 µm	 Similar woven fabric material with a reported mesh opening of 200 µm	The subject device uses Estene® Polyester thread (natural color) for its woven filter fabric with a calculated mesh opening of 180 µm, while the predicate device uses a similar woven fabric material with a reported mesh opening of 200 µm.
Provided Sterile	Yes (gamma radiation)	Yes (gamma radiation)	Same
Single Patient Use	Yes	Yes	Same
Implantable	No	No	Same
Relevant Testing Performed			
Biocompatibility Testing	Per ISO 10993-1: - Part 5 Cytotoxicity - Part 10 Intracutaneous Reactivity - Part 10 Irritation-Sensitization - Part 11 Systemic Toxicity - Part 11 Pyrogenicity	ISO 10993-1	Same
Device Sterilization	ISO 11137-1,-2	ISO 11137	Same
Device Packaging and Shelf-Life	ASTM F1980 ASTM F1140-07 ASTM F1929-15	Not known.	Device packaging and shelf have been validated for the subject device in accordance with the referenced ASTM standards.
Device Performance Testing	ISO 80369-1 ISO 80369-7 ISO 80369-20	Implosion Tubing Connection Tensile Strength Mechanical Plugging	
Animal Testing	NA	NA	Same
Clinical Testing	NA	NA	Same
Risk Analysis	ISO 14971	Not Known.	An appropriate Risk Analysis

			has been performed on the subject device.

5.9 Non-Clinical Performance Data

Genesis Biosystems has submitted LipiVage® and its packaging system for the appropriate biocompatibility testing per ISO 10993-1 and its applicable parts, sterilization validation per ISO 11137, accelerated aging per ASTM F1980, and performance testing per ISO 80369-1/-7. Adipose viability testing demonstrated that fat tissue viability was maintained. The subject device meets all internal Genesis Biosystems specification requirements to support substantial equivalence to the predicate device.

5.10 Clinical Performance Data

The performance and use of Suction Lipoplasty Systems classified under product code MUU and regulated within CFR 878.5040 has been well established in the clinical environment since the first such devices were cleared by the FDA. Therefore, there was no clinical testing required to support LipiVage®, as the indications for use is equivalent to the predicate device, which was not subjected to any clinical testing. The substantial equivalence of LipiVage® to the GID 700™ is supported by the non-clinical testing that was performed, along with other supporting documentation, and presented in this submission.

5.11 Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared device, or has the same intended use and different technological characteristics, but it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise any questions regarding its safety and effectiveness when compared to the predicate device.

LipiVage® has the same intended use and indications for use as the predicate device. The conclusions drawn from the data included in this submission, demonstrate that LipiVage® is as safe, as effective, and are substantially equivalent to the predicate device in intended use, indications for use, technological characteristics, mode of operation, mechanical performance, materials, biocompatibility and sterility, and is therefore substantially equivalent to the GID 700™.