February 9, 2023

Lipogems International S.p.A.
Attention: Carlo Russo
Viale Bianca Maria 24
Milan
Milano, Italy 20129

Re: BK220703 (Formally K142682)
Trade/Device Name: The Lipogems System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr Russo:

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 22, 2014. 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, Hosna Keyvan by email at hosna.keyvan@fda.hhs.gov.

Sincerely,

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

Enclosure

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 22, 2014

Lipogems International SpA
% Mr. Roger Gray
Donawa Lifescience Consulting Srl
Piazza Albania 10
00153 Rome
Italy

Re: K142682
Trade/Device Name: Lipogems System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: September 24, 2014
Received: September 25, 2014

Dear Mr. Gray:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

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)*
K142682

Device Name
Lipogems System

Indications for Use *(Describe)*
The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue for the purpose of transferring autologous adipose tissue for aesthetic body contouring (lipofilling) in applications including plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 in accordance with 21 CFR 807.92(c)

Device Name:	The Lipogems System
Type of 510(k) submission:	Traditional
Date of Submission:	16 September 2014
Manufacturer:	Lipogems International S.p.A. Viale Bianca Maria 24 20129 Milano MI) Italy
510(k) Owner:	Lipogems International S.p.A. Viale Bianca Maria 24 20129 Milano MI) Italy
Phone: **Fax:**	+39 02 3707 2408/9 +39 02 3707 2410
510(k) Submitter and Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	MUU
FDA Regulation Number:	878.5040
FDA Classification Name:	System, Suction, Lipoplasty
Classification Panel:	General and Plastic Surgery
Common Name:	Lipoplasty System
FDA Classification:	Class II
FDA Identification:	A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.

Indications for Use/Intended Use: The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue for the purpose of transferring autologous adipose tissue for aesthetic body contouring (lipofilling) in applications including plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.

Device Description:
The Lipogems System is a pre-assembled device consisting of:

- An ABS processing unit (Lipogems Processing Unit) containing 5 stainless steel spheres and 2 stainless steel sieve filters;
- An input washing line connected to the 'blue' side the processing unit;
- An access port for the loading of material to be processed with a Luer-lock connection and self-occluding valve (blue side ;
- A drain line connected to the gray side of the processing unit;
- An access port for the discharge of processed material with a Luer-lock connection and self-occluding valve (gray side);
- A bag for collecting waste material.

The Lipogems System Processing Unit is manufactured in two size variants with the same functional characteristics:

LGD 240: Lipogems Processing Unit with 240 cc capacity and standard exit sieve;
LGD 60: Lipogems Processing Unit with 60 cc capacity and standard exit sieve;

The intrinsic characteristics of the Lipogems fat treatment can be summarized as follows:

- Minimal handling of adipose tissue (only via mechanical action ;
- Maintenance of the vascular-stromal niches;
- Reduction of fat clusters to allow injection with fine needles, up to 27G;
- Removal of impurities, such as oil residues and blood.

The result of processing with the Lipogems System is a homogeneous and micronized fraction of adipose tissue, which allows a patient's subcutaneous fat to be processed for autologous reinjection within the operative procedure time.

There is no direct interaction of the device with the patient, although the adipose tissue that is processed in the device comes from the patient and is returned to the same patient after processing.

Interaction with other devices is necessary for operation of the Lipogems System, in particular, standard FDA cleared syringes are needed for the initial injection of adipose tissue into the processing unit, and for receiving the processed tissue upon completion of the processing steps.

The steps of operation of the Lipogems System are:

1. The Lipogems processing unit receives a constant gravity feed of physiological saline through the upper port. After first filling the processing unit with saline, adipose tissue is injected into the processing unit, where it undergoes a first reduction treatment and micronization of lipidic cluster as it passes through the input sieve.

2. The processing unit is then shaken manually, causing the spheres contained within the processing unit to exert mechanical action on the tissue/saline emulsion and further reduce the lipidic clusters, preserving the vascular-stromal niches, while the continuous flow of saline

eliminates oil and blood component residuals from the emulsion. The used saline is collected in the waste bag. Conducting the mechanical reduction while fully immersed in saline minimizes any traumatic action on the cells.

3. After completion of the shaking/washing step, the solution appears clear (at the top of the processing unit) and the lipoaspirate is yellow (at the bottom). The saline flow is then stopped and the device is inverted. A second adipose cluster reduction takes place by pushing the floating adipose clusters through the second sieve, pushing fluid from below with a syringe. The reduced clusters pass out of the now) top of the unit into a collecting syringe.

The materials used in the manufacture of the device are in common usage for medical devices. Testing in accordance with the relevant standards in the ISO 10993 series has demonstrated device biocompatibility.

100 % testing of device patency and freedom from leakage is carried out after manufacture and before terminal sterilization by ethylene oxide gas, resulting in a sterility assurance level (SAL) of 10^{-6}. The sterilization process has been validated in accordance with ISO 11135-1. The device is supplied for single use only.

A shelf life of five years has been established for the Lipogems System. This shelf life was established by exposing sterilized samples of the device to accelerated aging equivalent to five years real-time, in accordance with standard ASTM F1980.

Substantial equivalence:

Item	Predicate device	Subject device	Similarity
Device name	GID 700 Tissue Canister	The Lipogems System	N/A
Device Manufacturer	GID Group Inc	Lipogems International SpA	N/A
510(k) Reference	K120902	Not yet assigned	N/A
FDA Product Code	MUU	MUU	Same
FDA Classification Name	System, Suction, Lipoplasty	System, Suction, Lipoplasty	Same
FDA Regulation Number	878.5040	878.5040	Same
Indications for Use / Intended Use	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 reimplanted, 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.	The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue for the purpose of transferring autologous adipose tissue for aesthetic body contouring (lipofilling) in applications including plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.	Similar
Variations	One only: GID 700	Two: LGD 240, LGD 60	Different
System concept	Closed loop	Closed loop	Same
Construction	Preassembled	Preassembled	Same
Sterility	Supplied sterile for single use	Supplied sterile for single use	Same

Item	Predicate device	Subject device	Similarity
Sterilization method	Electron beam radiation	Ethylene oxide	Different
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Same
Biocompatibility	Biocompatible	Biocompatible	Same
Source of Energy	User supplied vacuum	None required	Different
Mechanical operation	Manual stirring mechanism comprising a propeller and a comb	Manual shaking of s/steel spheres	Different
Canister size	700 ml	240 or 60 ml	Different
Canister ports	Suction, vent, input, extraction	Saline feed, input, drainage, extraction	Similar
Tissue washing media	Lactated Ringers Solution	Physiological saline	Different
Mesh sizes	200 micron mesh to allow separation of waste products from adipose tissue - tissue does not pass through mesh	LGD 240 and LGD 60: 2000 micron mesh at inlet and 1000 micron mesh at outlet - collected adipose tissue passes though both meshes	Different
Unit testing	Implosion test	Leakage test	Different

The subject device and the predicate device share many identical or similar features and parameters. Differences exist in the following areas:

- Size variations
- Sterilization method
- Source of energy
- Mechanical operation
- Tissue washing media
- Filtering
- Unit testing

The most significant difference relates to the user manual shaking of the processing unit of the subject device in order to achieve adipose tissue reduction, whereas the predicate devices utilizes a rotary stirring action of a propeller and comb.

Substantial Equivalence Conclusion:
Based on the information contained in this submission, it is concluded that the Lipogems System is substantially equivalent to the identified predicate device which is already in interstate commerce within the USA.

Performance data:
The performance of the device is entirely controlled by the user and is not predetermined by the device itself. The instructions for use advise the user to process the tissue by waving and shaking the unit vigorously for a few minutes to emulsify the content. The instructions continue by identifying that when the processing phase is complete, fat tissue will appear compact, light yellow in color, floating on the transparent liquid phase.

Nonclinical testing:
The following nonclinical tests have been performed on the relevant components of the Lipogems system:

- Validation of the pre-assembly washing process carried out on the device spheres and sieves.
- Biocompatibility testing of all materials in the fluid path, including:
  - Cytoxicity (ISO 10993-5);
  - Sensitization (ISO 10993-10);
  - Intracutaneous Reactivity (ISO 10993-10);
  - Acute Systemic Toxicity (ISO 10993-11);
  - LAL bacterial endotoxin test.

- Validation of the sterilization process (ISO 11153-1
- Testing to validate a 5 year shelf life, including:
  - Peel strength;
  - Dye penetration;
  - Permeability.
- In-process patency and leakage testing of every device.