Lipogems International SpA
Attention: Carlo Russo
Lipogems International S.p.A.
Viale Bianca Maria 24
Milan
Milano 20129, Italy
Email Address: (b) (6) @lipogems.com

February 9, 2023

Re: BK220712 (Formally K171135)
Trade/Device Name: 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 May 18, 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, Candace Jarvis at (240) 402-8315 or by email at Candace.Jarvis@fda.hhs.gov.

Sincerely,

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

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

May 18, 2017

Lipogems International S.p.A.
% Scott Bruder, M.D., Ph.D.
Principal, Bruder Consulting International, LLC
268 Glen Place
Franklin Lakes, New Jersey 07417

Re: K171135
Trade/Device Name: Lipogems System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: April 14, 2017
Received: April 17, 2017

Dear Dr. Bruder:

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" (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.

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,

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)*

K171135

Device Name
The Lipogems System

Indications for Use *(Describe)*

The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue is desired: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery when aesthetic body contouring is desired. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be transferred, 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)

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

Device Name:	**The Lipogems System**
Type of 510(k) submission:	Traditional
Date of Submission:	May 3, 2017
510(k) Owner & Manufacturer:	Lipogems International S.p.A. Viale Bianca Maria 24 20129 Milano (MI) Italy Phone: +39 02 3707 2408/9 Fax: +39 02 3707 2410
510(k) Submitter and Contact:	Scott Bruder, MD, PhD Principal Bruder Consulting International, LLC 268 Glen Place Franklin Lakes, NJ 07417 Phone: 201.874.9701 Email: scottbruder@me.com
FDA Product Code:	MUU
FDA Regulation Number:	21 CFR 878.5040
FDA Classification Name:	System, Suction, Lipoplasty
Classification Panel:	General and Plastic Surgery
Common Name:	Lipoplasty System
FDA Classification:	Class II
Predicate Device:	K161636 The Lipogems System

Indications for Use / Intended Use:
The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue is desired: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery when aesthetic body contouring is desired. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be transferred, 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 color-coded end cap of the processing unit;

- An access port for the loading of material to be processed with a Luer-lock connection and self-occluding valve (color-coded end-cap);
- A drain line connected to the 'gray' end-cap of the processing unit;
- An access port for the discharge of processed material with a Luer-lock connection and self-occluding valve (gray end-cap);
- A bag for collecting waste material.

The Lipogems System Processing Unit is supplied sterile, for single use only, and 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 following Table provides a comparison and evidence of substantial equivalence of the subject device with the predicate device:

Predicate device comparison table			
Item	**Predicate device (Lipogems)**	**Subject device (Lipogems)**	**Similarity**
Device name	The Lipogems System	The Lipogems System	Identical
Device Manufacturer	Lipogems International SpA	Lipogems International SpA	Identical
510(k) Reference	K161636	Not yet assigned	N/A
Clearance Date:	November 4, 2016	Not yet assigned	N/A
FDA Product Code	MUU	MUU	Identical
FDA Classification Name	System, Suction, Lipoplasty	System, Suction, Lipoplasty	Identical
FDA Regulation Number	878.5040	878.5040	Identical
System concept	Closed loop	Closed loop	Identical
Device Size Variations	Two: LGD 60, LGD 240	Two: LGD 60, LGD 240	Identical
Fill Volumes	Up to 30 or 120 ml of fat	Up to 30 or 120 ml of fat	Identical
Construction	Preassembled	Preassembled	Identical
Sterility	Supplied sterile for single use	Supplied sterile for single use	Identical
Sterilization method	Ethylene oxide Gas	Ethylene oxide Gas	Identical
Sterility Assurance Level	SAL = 10^{-6}	SAL = 10^{-6}	Identical
Biocompatibility	Biocompatible	Biocompatible	Identical

Predicate device comparison table			
Item	**Predicate device (Lipogems)**	**Subject device (Lipogems)**	**Similarity**
Indications for Use / Intended Use	The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue is desired: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery when aesthetic body contouring is desired. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be transferred, the harvested fat is only to be used without any additional manipulation.	The Lipogems System is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue is desired: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery when aesthetic body contouring is desired. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be transferred, the harvested fat is only to be used without any additional manipulation.	Identical

Summary of technological Characteristics:
The subject device is identical to the predicate device in regards to:

- Indications/Intended Use
- Size variations
- Sterilization method
- Packaging
- Manufacturing
- Mechanical operation
- Tissue washing media
- Filtering
- Unit testing
- Fundamental scientific technology

Differences exist between the Subject and Predicate Device with regards to the addition of color-coded end caps in the Subject Device, and labeling changes to clarify the Instructions for Use. There have also been slight modifications in end cap and outer processing unit geometry. None of these modifications raise new questions of safety and efficacy.

Summary of Nonclinical testing:
Biocompatibility testing according to ISO 10993 was performed to confirm that the proposed modifications do not raise new questions of safety and/or efficacy. This included:

- Cytotoxicity (ISO 10993-5)
- Intracutaneous Reactivity* (ISO 10993-10)
- Delayed Hypersensitivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)

Substantial Equivalence Conclusion:
Based on the information contained within this submission, Lipogems International S.p.A. believes that the Lipogems System is substantially equivalent to the identified predicate device and does not introduce any new or significantly modified risks, and no new questions of safety and efficacy.