



Lipose Corporation  
Attention: Alan Curtis  
2647 Lin Gate Court  
Pleasanton, CA 94566

**February 9, 2023**

Re: BK220685 (Formally K081848)  
Trade/Device Name: LIPOSE FAT TRANSFER SYSTEM  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: Class II  
Product Code: QKL

Dear Mr. Curtis:

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 4, 2008. 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](mailto:Julia.Russell@fda.hhs.gov).

Sincerely,

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

Enclosures

6081848/s2 4/2

**5. 510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: December 4, 2008

510(k) number: \_\_\_\_\_

**DEC 04 2008**

**Applicant Information:**

Lipose Corp.  
280 Railroad Ave., Suite 200  
Greenwich, CT 06830

**Device Information:**

Trade Name:	Lipose Fat Transfer System
Classification:	Class II 21CFR 878.5040
Product Code:	MUU
Classification Name:	Liposuction Cannula

**Physical Description:**

The Lipose Fat Transfer System is a single-use disposable kit used in aspiration, harvesting, filtering, and transferring of autologous fat. The Lipose Fat Transfer System simplifies the collection and transfer autologous fat used in body contouring. The materials that comprise the Lipose Fat Transfer System are used routinely in similar devices and the predicate devices.

**Intended Use:**

The Lipose Fat Transfer System is intended to be used in the aspiration, harvesting, filtering and reinjecting of autologous fat.

**Equivalent Device:**

The subject device is substantially equivalent in intended use/technological characteristics and/or method of operation to:

- Tissu-Trans™ Syringe (K050797)
- Tulip Disposable Cannulas (K060089)
- Cytori AFT System (K072587)
- Genesis Biosystems, Lipivage™ Fat Harvest, Wash and Transfer System (K# unknown)

K081842 (5/2/2)

Lipose Fat Transfer System

510(k) Notification

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**Summary:**

Based on the intended use, materials, and technological characteristics information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Lipose Corporation  
% Mr. Alan Curtis, RAC  
2647 Lin Gate Court  
Pleasanton, California 94566

DEC 04 2008

Re: K081848

Trade/Device Name: Lipose Fat Transfer System  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: II  
Product Code: MUU  
Dated: October 23, 2008  
Received: October 24, 2008

Dear Mr. Curtis:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 – Mr. Alan Curtis

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K081848/52 4/1

Lipose Fat Transfer System

510(k) Notification

**4. INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): \_\_\_\_\_

Device Name: Lipose Fat Transfer System

Indications for Use:

The Lipose Fat Transfer System is intended to be used in the aspiration, harvesting, filtering and reinjecting of autologous fat.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K081848

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