Lipose Corporation   **February 9, 2023**
Attention: Alan Curtis
2647 Lin Gate Court
Pleasanton, CA 94566

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/RegistrationandList
ing/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