



HARVEST TECHNOLOGIES CORP.  
Attention: Connie Lucas  
Terumo BCT, INC.  
10811 West Collins Ave.  
Lakewood, CO 80215  
Email Address: (b) (6) @terumobct.com

**February 9, 2023**

Re: BK220696 (Formally K121005)  
Trade/Device Name: ADIPREP ADIPOSE TRANSFER SYSTEM  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: Class II  
Product Code: QKL, QUB

Dear Ms. Lucas:

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 September 21, 2012. 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](mailto:Candace.Jarvis@fda.hhs.gov).

Sincerely,

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