



SHIPPERT MEDICAL TECHNOLOGIES CORP.

February 9, 2023

Attention: Kevin McIntosh  
Summit Medical, LLC  
815 Vikings Parkway, Suite 100  
Saint Paul, MN 55121

Re: BK220688 (Formally K092482)  
Trade/Device Name: TISSU TRANS FILTRON MODELS 3-TT-FILTRON 2000-500  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: Class II  
Product Code: QKL

Dear Mr. McIntosh:

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, 2009. 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](mailto:hosna.keyvan@fda.hhs.gov).

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

Sincerely,

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

Enclosure