



ANDREW TECHNOLOGIES LLC
Attention: Casey Cramer
Spartronics Strongsville Inc.
22740 Lunn Road
Strongsville, OH 44149
Email Address: (b) (6) [@spartronics.com](mailto:(b) (6)@spartronics.com)

February 9, 2023

Re: BK220698 (Formally K130152)
Trade/Device Name: HYDRASOLVE LIPOPLASTY SYSTEM
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL, QUB

Dear Ms. Cramer:

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 April 18, 2013. 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/cm053185.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