ANDREW TECHNOLOGIES LLC **February 9, 2023**
Attention: Casey Cramer
Spartronics Strongsville Inc.
22740 Lunn Road
Strongsville, OH 44149
Email Address: (b) (6) @spartronics.com

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/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.

Sincerely,

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

A.4. 510(k) Summary

APR 18 2013

Submitted by:	Herbert Crane Vice President Regulatory Affairs and Quality Assurance
Address:	Andrew Technologies 3 Haddon Avenue Haddonfield, NJ 08033
Telephone:	(959) 502-1907
Facsimile:	(856) 433-8092
Date of Submission:	17 January 2013
Classification Name: Device Product Code	Suction Lipoplasty System (21 CFR 878.5040) MUU
Trade or Proprietary or Model Name:	HydraSolve™ Lipoplasty System
Legally Marketed Devices:	HydraSolve™ Lipoplasty System (K121218) Harvest AdiPrep Adipose Transfer System (K121005)

Device Description:
The Andrew Technologies HydraSolve™ Lipoplasty System is a liposuction system used to perform body contouring. It is designed to perform selective tissue extraction through a cannula that utilizes pressurized, heated, and pulsed saline solution in addition to suction. Adipose tissue aspirated with the HydraSolve™ Lipoplasty System can be harvested for subsequent autologous transfer.

The device includes the HydraSolve™ Console which contains within its durable case: a user interface, controller, power supply, and Phaser™ energy transfer systems (both heat and pressure). The system also includes a tumescent infusion component which is compatible with commercial off-the-shelf (COTS) tumescent cannulae and tubing. The device also includes the Sterile Treatment Kit consisting of a pumping mechanism, heat exchanger and tubing and a reusable limited-use handpiece with integral cannula. The device interfaces with COTS waste canisters and suction tubing.

Indications for Use:
The HydraSolve™ Lipoplasty System is intended to be used for liquefaction and aspiration of localized subcutaneous fatty deposits for the purpose of aesthetic body contouring. Adipose tissue harvested with the HydraSolve™ Lipoplasty System may be used for autologous transfer following the method provided in the manual.

Comparison to Predicate Device
A table comparing the technological characteristics of the subject device and predicate devices is included as a third page of this Summary of Safety and Effectiveness. With the exception of the Indications for Use statement, the subject device is identical to the predicate device cleared under K121218.

Summary of testing to demonstrate safety and effectiveness

Nonclinical test data was used to support the decision of safety and effectiveness. Clinical testing was not necessary. Non-clinical testing consisted of testing aspirated adipocyte cell viability fat graft survivability, and fat graft quality.

Conclusion

The information provided in this submission demonstrates that the device is substantially equivalent to the predicate devices.

510(k) Summary
Substantial Equivalence Comparison to Predicate Devices

ATTRIBUTE	SUBJECT DEVICE	PREDICATE	PREDICATE
	HydraSolveTM Lipoplasty System (AFT Indication)	Harvest AdiPrep (K121005)	HydraSolve™ Lipoplasty System (K121218)
User Population	**Trained Medical Professionals**	Trained Medical Professionals	Trained Medical Professionals
Major Components	- **System Console** - **Wetting Infusion Unit** - **Aspiration Unit** - **Phaser Stream Heating and Pumping Unit** - **Phaser Cannula** - **Aspirate Collection Unit**	- Syringes with removable plunger - Centrifuge tubes with filter - Aspiration & fat injection cannula - Fat injection syringes - Skin puncture needles - Oil extraction syringe & needle	- System Console - Wetting Infusion Unit - Aspiration Unit - Phaser Stream Heating and Pumping Unit - Phaser Cannula - Aspirate Collection Unit
Technological Characteristics	**Pressurized, heated, and pulsed saline to liquefy fatty deposits while aspiration is engaged to remove liquefied material**	N/A	Pressurized, heated, and pulsed saline to liquefy fatty deposits while aspiration is engaged to remove liquefied material
Intended Use	**Aesthetic Body Contouring**	Aesthetic Body Contouring	Aesthetic Body Contouring
Tissue Processing & Implantation Technique	**Concentration of aspirated adipose tissue using a centrifuge followed by injection using a syringe**	Concentration of aspirated adipose tissue using a centrifuge followed by injection using a syringe	N/A
Indications for Use	**The HydraSolve™ Lipoplasty System is intended to be used for liquefaction and aspiration of localized subcutaneous fatty deposits for the purpose of aesthetic body contouring. Adipose tissue harvested with the HydraSolve™ Lipoplasty System may be used for autologous transfer following the method provided in the manual.**	The AdiPrep Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The AdiPrep system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The AdiPrep Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired. Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, Arthroscopic Surgery	The HydraSolve™ Lipoplasty System is intended to be used for liquefaction and aspiration of localized subcutaneous fatty deposits for the purpose of aesthetic body contouring. The HydraSolve™ Lipoplasty System is indicated for use in aesthetic body contouring.

K130152 page 3 of 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Andrew Technologies
% Mr. Herbert Crane
Vice President, Regulatory Affairs and
Quality Assurance
3 Haddon Avenue
Haddonfield, New Jersey 08033

April 18, 2013

Re: K130152
Trade/Device Name: HydraSolve™ Lipoplasty System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: March 29, 2013
Received: April 01, 2013

Dear Mr. Crane:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A.3.

Indications for Use

510(k) Number (if known): K130152

Device Name: **HydraSolve™ Lipoplasty System**

Indications For Use:

The HydraSolve™ Lipoplasty System is intended to be used for liquefaction and aspiration of localized subcutaneous fatty deposits for the purpose of aesthetic body contouring. Adipose tissue harvested with the HydraSolve™ Lipoplasty System may be used for autologous transfer following the method provided in the manual.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130152