K092284 Page 1/2

M.D. RESOURCE

Food and Drug Administration
Center for Device and
Radiological Health
HFZ-401
9200 Corporate Blvd
Rockville, MD 20850

SEP - 1 2009

July 24th, 2009

Dear Sir/Madam,

Delineated below is the 510(k) Summary:

Date prepared:	July 24th, 2009	
510(k) Owner / Preparer / Official Contact:	Melbourne Kimsey II 23392 Connecticut Street Hayward, Ca. 94545 510.909.7882 Mobile 510.732.9950 Office 510.785.8182 Fax	
Manufacturer:	Medical Device Resource Corporation	
Trade Name:	LipiSystems AquaVage	
Common Name:	Sterile canister system	
Classification Name:	Suction Lipoplasty System, Class II - 21 CFR § 878.5040, Product Code: MUU 21 CFR 880.6960 – Syringe, Class I (Sterile), Product Code: KYZ	
Legally marketed device:	K081593 - LS Liposuction Aspirator	
Description of Device:	Device function:	1. Contains port interfaces between: Canister to tubing & aspirator to canister. 2. Sterile tubing to connect the interfaces 3. Funnel to interface port to tubing. 4. Syringe to collect fat.
	Device design:	1. Contents subjected to sterility
	Material used:	Plastic Canister, Syringe, silicone tubing

	Physical properties: Plastic & Silicone
Intended Use of the Device:	For use in aspirating subcutaneous fatty tissue including autologous fat collection.
Patient population for which the device is intended:	Patients who desire aesthetic body contouring and autologous fat collection

510(k) Summary continued...

Technological characteristics:	Same as predicate except canister is sterilized
Determination of substantial equivalence:	SE to the predicate device was based on non-clinical data. Performance and function supported the determination of SE.
Conclusions for safety, effectiveness, and performance of the device:	Predicate device demonstrates safety/effectiveness. Conclusions have been drawn that the device is SE and therefore safe & effective. The device performs better than predicate due to addition of sterilized canister system.

Sincerely,

Melbourne Kimsey II
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medical Device Resource Corporation
% Mr. Melbourne Kimsey II
President
23392 Connecticut Street
Hayward, California 94545

March 21, 2013

Re: K092284
Trade/Device Name: Lipisystems Aquavage Model AV2000 & 1200
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU, KYZ
Dated: July 24, 2009
Received: August 7, 2009

Dear Mr. Kimsey:

This letter corrects our substantially equivalent letter of September 1, 2009.

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 (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.

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

DEA K000003

Indications for Use

510(k) Number (if known): K092284

Device Name: Lipisystems Aquavage Model AV2000 & 1200

For use in aspirating subcutaneous fatty tissue including autologous fat collection.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092284