

JUL 23 2008

## 510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

The assigned 510(k) number is: K081593

1. **Submitter Information:**

Prepared: May 12<sup>th</sup>, 2008  
Contact Person: Melbourne Kimsey II, President  
Est. Reg. #: 2938001  
Medical Device Resource Corporation  
23392 Connecticut Street, Hayward, CA 94545  
510.732.9950 T / 510.785.8182 F

2. **Name of Device:**

LS Liposuction Aspirator

**Proprietary Name:**

LS2 Liposuction Aspirator

**Common Name:**

Aspirator Pump, Powered Suction Pump, Power Aspirator, Liposuction Aspirator

3. **Classification:**

Suction Lipoplasty System, Class II - 21 CFR § 878.5040 (2008)  
Aspirator, Apparatus, Suction, Operating Room, Wall Vacuum Powered, Class II - 21 CFR § 878.6740 (2008)  
Aspirator, Apparatus, Suction, Ward Use, Portable, AC-Powered, Class II - 21 CFR § 878.4780 (2008)

4. **Product Code:** MUU

5. **Substantial Equivalence:**

The LS Liposuction Aspirator(s) are believed to be substantially equivalent to the aspiration devices listed below in terms of intended use, design, operating principles, materials, performance, with a **change of intended use:**

M.D. Resource: K854844  
Byron Medical: K980392  
Byron Medical: K981215  
HK: K032802

6. **Device Description:**

The LS Liposuction Aspirator is a powered suction pump/ aspirator which uses an electrically (AC) driven vacuum pump generating a negative pressure for the removal of fat/ adipose (Suction Lipoplasty), soft tissue, and general surgical waste.

7. **Intended Use:** Aesthetic Body Contouring



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 23 2008**

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

Re: K081593  
Trade/Device Name: LS Liposuction Aspirator Pump  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: II  
Product Code: MUU  
Dated: May 22, 2008  
Received: June 6, 2008

Dear Mr. Kimsey:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 – Mr. Mel Kimsey

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

510K Number: K081593

Device Name: LS Liposuction Aspirator Pump

Indications For Use: The LS Liposuction Aspirator is for aesthetic body contouring.

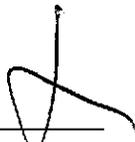
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Concurrence of CDRH, Office of Device Evaluation (ODE)

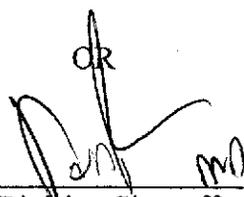
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number \_\_\_\_\_

Prescription Use 

OR

Over-the-Counter Use \_\_\_\_\_

  
Division Sign-off  
Division of General, Restorative  
and Neurological Devices

510(k) Number 1L081593