

AUG 25 2006

1/2

**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 K053451"

**1. Submitter Information:**

Möller Medical GmbH & Co. KG  
Wasenkuppenstrasse 29-31  
D36011 Fulda  
Germany

Contact person:

Bill Kelley  
2381 Via Monte  
Coto de Caza, CA 92679-4001  
Phone: (949) 292-8477  
Fax: (509) 479-4840

**2. Name of Device:**

Common Name: Suction Lipoplasty System

Proprietary Name: Liposat® (infiltration pump), model # 00 002 274.

Vacusat® (aspiration/suction pump), model # 00 002 252 (220 V) and  
model # 00 002 318 (110 V).

Vibrasat® (vibration handpiece for the liposuction cannula), model #  
00 002 246.

**3. Classification:**

Suction Lipoplasty System, Class II  
21 CFR § 878.5040 (1998)

**4. Product Code:**

MUU

**5. Substantial Equivalence:**

The Möller Medical Suction Lipoplasty System is substantially equivalent to the aspiration devices listed below in terms of intended use, design, operating principles, and materials.

HK Surgical, Inc.:	K032802
Byron Medical, Inc.:	K981172, K001803
MicroAire Surgical Instruments:	K981922

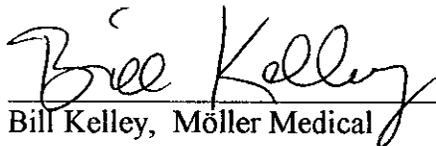
**6. Device Description:**

The Möller Medical Lipoplasty System is an electrically powered infiltration/peristaltic pump combined with an aspiration/vacuum pump and manual or vibrating cannula hand-piece, tubing sets and waste containers for the removal of fat tissue and general surgical waste.

**7. Intended Use:**

Aesthetic Body Contouring

**8. Signature of Applicant:**

  
\_\_\_\_\_  
Bill Kelley, Möller Medical



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 25 2006**

Moeller Medical GmbH & Co. KG  
% Moeller Medical  
Mr. Bill Kelley  
23832 Via Monte  
Coto De Caza, California 92679-4001

Re: K053451  
Trade/Device Name: Suction Lipoplasty System  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: II  
Product Code: MUU  
Dated: July 14, 2006  
Received: July 28, 2006

Dear Mr. Kelley:

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.

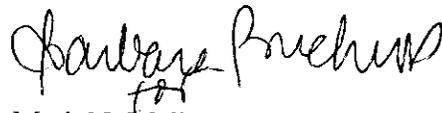
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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. Bill Kelley

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with some loops and flourishes.

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

Enclosure

K053451

**Indications for Use**

510(k) Number (if known): K053451

Device Name: Suction Lipoplasty System

Indications for Use: For aesthetic body contouring.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K0 Barbara Brudnick  
(Division Sign-Off) *for MCM*

Page 1 of 1

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K053451