Moeller Medical Gmbh & Co. Kg
Bill Kelley
23832 Via Monte
Coto De Caza, California 92679-4001

June 8, 2021

Re: K053451
Trade/Device Name: Liposat (infiltration Pump), Model 00 002 274; Vacusat (suction Unit), Model 00 002 252 (220 V), 00 002 318 (110 V);
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Bill Kelley:

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 August 25, 2006. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 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.

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,

for

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___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

for MKM

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

510(k) Number K053451

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AUG 25 2006

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
Wasserkuppenstrasse 29-31
D36043 Fulda
Germany

Contact person:

Bill Bailey
23811 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)

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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/peristalitic 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

Bill Kelley, Möller Medical