Medela Ag
Werner Frei
Mgr., RA
Laettichstrasse 4b
Baar, Zug, CH-6341
Switzerland

June 8, 2021

Re: K063336
Trade/Device Name: Medela Dominant 50 Lipo, Model 600-5706
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Werner Frei:

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 February 26, 2007. 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

Medela AG
% Mr. Bruno Gretler
Regulatory Affairs
Laettichstrasse 4b
6341 Baar
Switzerland

FEB 26 2007

Re: K063336
Trade/Device Name: Medela® Dominant 50 Lipo, Model 600-5706
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplarty system
Regulatory Class: Class II
Product Code: MUU
Dated: January 30, 2007
Received: January 31, 2007

Dear Mr. Gretler:

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,

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

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Medela® Dominant 50 Lipo

Indications For Use:
The Medela® Dominant 50 Lipo is intended to be used 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Pol for MKM

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

510(k) Number K063336

Applicant: Medela AG, Laettichstrasse 4b, CH-6341 Baar, Switzerland
Contact Person: Werner Frei, Tel +41 (41) 769 51 51 ext. 228; Fax +41 (41) 769 51 00
werner.frei@medela.ch
Traditional 510(k) Submission for Medela® Dominant 50 Lipo

FEB 26 2007

Section E - 510(k) Summary

This 510(k) summary for the **Medela® Dominant 50 Lipo** Powered Suction Pump meets the requirements of 21 CFR 807.92.

1 Sponsor's Name, Address and Contact Person

Sponsor:
Medela AG
Medical Equipment
Laettichstrasse 4b
6341 Baar
Switzerland
Ph: +41 41 769 5151 ext. 228
Fax: +41 41 769 5100

Contact Person
Werner Frei
Manager Regulatory Affairs

Date Summary Prepared: November 2, 2006

2 Name of Device

Trade Name:	**Medela® Dominant 50 Lipo** Secretion & Surgical Aspirator
Common Name:	Powered Suction Pump Dominant 50 Lipo
Classification Name:	SUCTION LIPOPLASTY SYSTEM Classified Class II, per 21 CFR Section 878.5040
Product Code:	MUU

3 Name of the predicate Device(s)

- Medela® Basic, Median, Dominant, Vario Suction Pumps, by Medela Inc.
  K021368
- HK Liposuction Aspirator, Model AP-III & AP230-III, by HK Surgical Inc.
  K032802
- Vacusat® (Aspiration/Suction Pump), Model # 00 002 252 and Model # 00 002 318, by Moeller Medical GmbH & Co. AG
  K053451

4 Device Description

The **Medela® Dominant 50 Lipo** Suction Pump is identical to original and approved Medela Dominant 50 Secretion Aspirators (K021368), which is all based on the well-proven Medela piston-cylinder system.

The **Medela® Dominant 50 Lipo** suction pump is an AC powered aspirator and incorporates in its housing an AC-motor with a flat belt power transmission to the pistons and cylinders, an ON/OFF-switch, a vacuum gauge in kPa and mmHG, a membrane vacuum regulator, a safety device of polysulfone with an overflow protection device and connection tubing, an electric cord and an instruction manual.

The standard mobile version includes a mobile stand with fitting rails 10 x 25 mm, 4 anti-static castors, two with locking device and an integrated ON/OFF foot switch. The **Medela® Dominant 50 Lipo** also comes in rack versions i.e. without handle and cable holder for storage/operation in racks with reduced space.

This notification for the **Medela® Dominant 50 Lipo** Suction Pump is for labeling change and to include additional indications. There have been no modifications or design changes to the currently cleared and marketed **Medela® Dominant 50,** 510(k) No. K021368.

The **Medela® Dominant 50 Lipo** Suction Pump is a further innovative development of Medela's well-proven piston/cylinder system. The drive power is transferred to the piston/cylinder modules. The required suction value is rapidly built-up. High suction performance and low weight are positive features of the Vario pump.

> The **Medela® Dominant 50 Lipo** suction pump has a suction capacity of 50 liters per minute and a maximum vacuum up to -90 kPa (-675 mmHg). The pump is marked "high vacuum – high flow".

A variety of reusable and disposable accessories are available. A variety of cannuals for various liposuction procedures and aesthetic body contouring are also available.

5 Indications for use

The **Medela® Dominant 50 Lipo** Suction Pump is intended to be used for aesthetic body contouring.

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6 Summary of Technological Characteristics

The **Medela® Dominant 50 Lipo Suction Pump** is identical in construction and performance to the legally marketed device as submitted under FDA File Number K021368 - there are no technical differences which would raise new aspects regarding safety and effectiveness.
The only modification relates to a more differentiated trade name - **Medela® Dominant 50 *Lipo*** instead of **Medela® Dominant 50** only (Lipo reflects the intended use).

7 Conclusion

According to the FDA Guidance „Deciding When to Submit a 510(k) for a Change to an Existing Device", the modification mentioned above does not affect the safety or effectiveness of the device (e.g. a significant change or modification in design, material, chemical composition, energy source or manufacturing process). All conclusions are made by the decision making process according above mentioned guidance document.

Based upon the information presented above and in this 510(k) submission, it is concluded that the proposed **Medela® Dominant 50 Lipo** suction pump is substantially equivalent, reliable, safe and effective for the intended use.