K080357 pg 1 of 3

Applicant: Medela AG, Laettichstrasse 4b, CH-6341 Baar, Switzerland
Contact Person: Bruno Gretler, Tel +41 (41) 769 51 51 ext. 247; Fax +41 (41) 769 51 00
bruno.gretler@medela.ch
Traditional 510(k) Submission for Medela® INVIA Wound Therapy

JUL 24 2008

Section E - 510(k) Summary

This 510(k) summary for the **Medela® INVIA Wound Therapy** 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. 247
Fax: +41 41 769 5100

Contact Person
Bruno Gretler
Manager Regulatory Affairs

Date Summary Prepared: February 06, 2008

2 Name of Device

Trade Name:	**Medela® INVIA Liberty** Secretion & Surgical Aspirator
Common Name:	Powered Suction Pump
Classification Name:	PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED) Classified Class II, per 21 CFR 878.4780
Product Code:	JCX

3 Name of the predicate Device(s)

- **Medela® Vario 8/18/ci** Suction Pumps, by Medela AG
  K061205
- **KCI V.A.C. Freedom**, by KCI KINETIC CONCEPTS, INC.
  K032310

Applicant: Medela AG, Laettichstrasse 4b, CH-6341 Baar, Switzerland
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4 Device Description

The **Medela® INVIA Liberty** pump is an innovative suction pump to help promote wound healing. Its well-proven membrane system guarantees maximum suction performance and quiet, dependable operation. Additional advantages of the **Medela® INVIA Liberty** are: user friendliness, patient mobility, simple cleaning and integrated safety features. A comprehensive range of accessories makes the **Medela® INVIA Liberty** ideally suited for Negative Pressure Wound Therapy (NPWT).

The **Medela® INVIA Liberty** suction pump is an AC/DC powered, maintenance-free aspirator for Negative Pressure Wound Therapy which incorporates a DC-motor with membrane aggregate power actuation in its housing. A user friendly MMI (man machine interface) guides the user through first installation, change of settings, use, data transfer and alarm handling.

The **Medela® INVIA Liberty** suction pump has an electronic measuring and monitoring system with optical and acoustic status display. It is a "medium vacuum" suction pump and has a suction capacity of 5 liters per minute and a maximum vacuum up to -27 kPa (-200 mmHg). The pump is marked "low flow – medium vacuum".

A variety of reusable and disposable accessories to help promote wound healing are available.

5 Indications for use

The **Medela® INVIA Wound Therapy** is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Annotation:
*The **Medela® INVIA Liberty** is used as vacuum source for the **Medela® INVIA Wound Therapy** in combination with the system components and accessories for Negative Pressure Wound Therapy.*

6 Summary of Technological Characteristics

The **Medela® INVIA Liberty** suction pump is working with a membrane aggregate, an electronic vacuum regulator and has a digital display. It has the identical performance characteristics and is equipped with the identical technology like the predicate devices and other legally marketed devices. The technological features do not affect safety and effectiveness of the device or the application (to help promote wound healing).

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7 Conclusion

There are no differences in performance or technology which significantly affect the safety and effectiveness of the device or the application "to help promote wound healing". All conclusions are made by the decision making process according to the recommendations in the "510(k) SE Decision Making Process" document.

The **Medela® INVIA Liberty** suction pump has the identical intended uses and, where applicable, the identical technological characteristics and performance data as the predicate devices.

Based upon the information presented in this submission, it is proven that the proposed **Medela® INVIA Liberty** powered suction pump is substantially equivalent, safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Medela AG
% Mr. Scott Cohn
1101 Corporate Drive
Mchenry, Illinois 60050

Re: K080357
Trade/Device Name: Medela® INVIA Wound Therapy
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: June 23, 2008
Received: June 17, 2008

Dear Mr. Cohn:

This letter corrects our substantially equivalent letter of July 24, 2008.

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); 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 continue 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). 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/dsma/dsmamain.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

K080357

Indications for Use

510(k) Number (if known):

Device Name: Medela® INVIA Wound Therapy

The Medela® INVIA Wound Therapy is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

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)

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

510(k) Number K080357