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Section E - 510(k) Summary

Medela Powered Suction Pumps

Dominant 35 c/i

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: October 10, 2004

2 Name of Device

Trade Name:	**Medela® Dominant 35 c/i** Secretion & Surgical Aspirator
Common Name:	Powered Suction Pump
Classification Name:	PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED) (Classified Class II, per 21 CFR Section 878.4780).

3 Name of the predicate Device(s)

- Medela® Basic 30 & Dominant 50 Suction Pumps, by Medela Inc. K021368
- Aeros Moblvac III Aspirator, by Aeros Instruments, Inc. K933902

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4 Description of Device

The Dominant 35 c/i Powered Suction Pump is an advancement of the approved Medela® Basic 30 and Dominant 50 Series of Secretion and Surgical Aspirators, which are all based on the well-proven Medela piston-cylinder system.
The Dominant 35 c/i Powered Suction Pump provides the choice of two suction modes:

- Constant Suction (c) with a flow rate of 35 liters/min (high flow)
- Intermittent Suction (i) with a flow rate of 8 liters/min (low flow) and default settings of 16 seconds ONTime / 8 seconds OFFTime.

The new Dominant 35 c/i is based on the Dominant 50 and has additionally fixed to it's housing a jar holder which guarantees that the jar is approximately 20 cm above patient level.
The Dominant 35 c/i is an AC-powered aspirator and incorporates an AC-motor with gearbox, pistons and cylinders, an operation panel, a vacuum gauge in kPa and mmHG, a self-bleeding membrane vacuum regulator, a safety device of polysulfone with overflow protection device and connection tubing, an electric cord and an instruction manual.
The standard version includes a mobile stand with fitting rails 10 x 25 mm and four antistatic castors, two with locking device. The internal and external foot "ON/OFF"-switches have been retained unchanged, but please note, that these switches are only active while working in the constant mode!

5 Intended Use of the Device

The Dominant 35 c/i is intended to be used for a variety of suctioning procedures including nasopharyngeal, tracheal, surgical, wound and thoracic drainage (must be used only in combination with a chest drainage unit with a built in flow adjustment valve). The intermittent suction mode is intended to be used for gastrointestinal suction procedures.
The pump is highly suitable for gastrointestinal suction procedures and for all routine suctioning procedures involving surgical and bodily fluids, gases, blood, secretions, tissue (including bone) and infectious materials in operating theatres, emergency rooms, physicians offices, at the patients bedside and is also to perform wound and thoracic drainage. A comprehensive range of accessories makes the Dominant 35 c/i ideally suited to a wide range of medical applications.

The intended uses and the indications of the Medela Dominant 35 c/i powered suction pump, are the same as the intended uses and indications for the predicate devices Medela Basic 30 and Dominant 50 suction pumps (K021368) and/or to the AEROS Mobivac III (K933902).

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6 Summary of Technological Characteristics

The Dominant 35 c/i is based on the Dominant 50, with an additional operation panel to choose either constant or intermittent mode and – if desired – to change the time settings in the intermittent mode.
The technology of the Dominant 35 c/i powered suction pump is identical to the legally marketed (unmodified) devices and there are no technical differences which would raise new aspects regarding safety and effectiveness.

7 Conclusion

Based upon the information presented above, it is concluded that the proposed **Medela® Dominant 35 c/i** powered suction pump is 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

JAN - 7 2005

Medela AG
c/o Mr. Stefan Preiss
TÜV Product Service, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55412

Re: K043544
Trade/Device Name: Dominant 35 c/i
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: December 21, 2004
Received: December 23, 2004

Dear Mr. Preiss:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Dominant 35 c/i

Indications For Use:

The Dominant 35 c/i Suction Pump is indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from wounds or from a patient's airway or respiratory support system, either during surgery or at the patients bedside. Generally the Dominant 35 c/i is intended to be used for a variety of suctioning procedures including nasopharyngeal, tracheal, surgical, gastrointestinal, wound and thoracic drainage (must be used only in combination with a chest drainage unit with a built in flow adjustment valve) in either "constant" or "intermittent" mode.

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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043544