K033179

Applicant: Medela AG, Laettichstrasse 4b, CH-6341 Baar, Switzerland
Contact Person: Werner Frei, Tel +41 (41) 769 5151 ext. 228; Fax +41 (41) 769 5100
werner.frei@medela.ch
Abbreviated 510(k) Submission for Medela® CLARIO™ Home Care Pump

OCT 15 2003

Section G - 510(k) Summary

Medela Powered Suction Pumps, Model "CLARIO"

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: May 01, 2003

2 Name of Device:

Trade Name: **Medela® CLARIO** Home Care Pump
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 legally marketed Device(s):

Medela® Vario Suction Pumps, by Medela Inc., K983552

Heavy Duty (HD) Suction Units (Atmos LC 16) by Jedmed Instrument Co, K862569

605 VACU-MAX, by Medical Industries America, Inc., K941961

Power Pack Suction, Ambu International A/S, K932031

4 Description of Device:

The Clario suction pump consists of three parts: drive unit, SafetyChamber (valve block) and canister set.

The DC motor and gear, drive electronics, LED light (indicating battery status), the on/off switch and, in the AC/DC version, a rechargeable battery are housed in the drive unit.

The valve block is attached to the drive unit with a turning motion. Two valve discs in the block are responsible for building up the vacuum in the suction canister.

On the top of the valve block the vacuum level can be adjusted by the user by means of a rotating knob, selecting one of the three air bleeding orifice sizes.

The canister set consists of canister, lid and swimmer. The canister plugs directly into the valve block.

For operation off the mains supply a medical grade AC/DC adapter is included.

5 Intended Use of the Device:

The Medela Clario Home Care Pump is intended for use in the medical field for suctioning secretions, bodily fluids and foreign objects in the nasal, pharyngeal and tracheal areas.

6 Summary of Technological Characteristics:

The technology of the Clario Home Care Pump is identical to the predicate 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 CLARIO Home Care Pump is safe and effective for the intended use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 5 2003

Medela AG
C/o Mr. Stefan Preiss
TÜV America, Inc.
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K033179
Trade/Device Name: Medela® CLARIO™ Home Care Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: September 29, 2003
Received: October 1, 2003

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 (301) 594-4659. 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,

for Mark N. Melkerson

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

510(k) Number (if known):_____

Device Name: Medela "CLARIO"

Indications For Use:

The Medela CLARIO Suction Pumps are indicated for aspiration and removal of secretions, bodily fluids and foreign objects from a patient's airway or respiratory support system in the nasal, pharyngeal and tracheal areas.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K033179

(Optional Format 3-10-98)