JUN - 6 2003

K031614

Section E – 510(k) Summary

Medela® Pump in Style® Advanced Breastpump

1. Sponsor's Name, Address and Contact Person:

Sponsor:
Medela Inc.
1101 Corporate Drive
McHenry, IL 60050
Ph: (815) 363 1166 ext. 280
Fax: (815) 363 0460

Contact Person:
Christopher L. Peterson
Director Quality Management and
Regulatory Affairs

Date Summary Originally Prepared: January 27, 2003

2. Name of Device:

Trade Name: Medela® **Pump in Style® Advanced** Breastpump
Common Name: Powered Breast Pump
Classification Name: Powered Breast Pump (Classified Class II, per 21 CFR section 884.5160).

3. Name of Predicate Device(s):

Medela® Symphony® Breast Pump, by Medela Inc., K020518
Medela® Pump in Style® Breastpump, by Medela Inc., K950750

4. Description of Device:

The Medela® Pump in Style® Advanced Breastpump is intended to express the mother's milk of a lactating woman. The pumping can be performed on one breast or on both breasts at the same time. The Pump In Style® Advanced Breastpump employs a diaphragm-type vacuum pump, powered by a DC motor supervised by a microcontroller. The microcontroller drives the "H" bridge, providing speed and directional control over the DC motor. The Pump In Style® Advanced Breastpump can be powered by external batteries or a wall plug transformer or by a 12 VDC vehicle lighter adapter.

The control program resides in a microcontroller, inside the Pump In Style® Advanced Breastpump and provides the necessary a) time and b) vacuum parameters. By adjusting the knob, the microcontroller changes the vacuum and time parameters of the suction. The breast pump is capable of providing vacuum levels from 0 to 250mm Hg, with cycling rates up to 120 cycles per minute. The program residing on the microcontroller is designed to deliver two pumping curves.

All materials with milk contact or components with human breast contact are manufactured from materials that meet the appropriate FDA and international regulations concerning food contact and/or biocompatibility.

5. Intended Use of the Device:

The Pump In Style® Advanced Breastpump is intended to express and collect the mother's milk from the breasts of a lactating woman, thus it is identical to the predicate devices.

6. Summary of Technological Characteristics:

The technology of the Pump In Style® Advanced Breastpump 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 Pump In Style® Advanced Breastpump 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

JUN - 6 2003

Medela, Inc.
% Mr. Stefan Preiss
Responsible Third Party
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K031614
Trade/Device Name: Pump in Style® Advanced Breastpump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: 85 HGX
Dated: May 23, 2003
Received: May 23, 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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K031614**

Device Name: **Medela® Pump in Style® Advanced Breastpump**

Indications For Use:

The Pump in Style® Advanced Breastpump is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031614

Over-the-Counter Use ✓