K053052

Section E - 510(k) Summary

MAY 2 2006

Medela® Swing™ Breastpump

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

Medela AG
Laettichstr. 4b
6341 Baar
Switzerland
Ph: +41 (0)41 769 5151
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Contact Person:
Werner Frei
Manager Regulatory Affairs

Date Summary Prepared: July 20, 2005

2. Name of Device:

Trade Name:	Swing™
Common Name:	Powered Breast Pump
Classification Name:	Powered Breast Pump (Classified Class II, per 21 CFR Section 884.5160)

3. Name of Predicate Device:

Medela® Symphony® Breastpump, by Medela AG, K020518
Medela® Mini Electric® Breastpump, by Medela AG, K901344

4. Description of Device:

The Medela® Swing™ Breastpump is intended to express the mother's milk of a lactating woman. The pumping can be only on one breast at the time.
The Swing™ breastpump can operate off common batteries or off an AC/DC power supply. The Swing™ breastpump's drive unit employs a diaphragm-type vacuum pump, powered by a DC-motor, supervised by a microcontroller. The microcontroller provides control over motor speed (vacuum creation) and solenoid (vacuum release).

The control program resides in a microcontroller, inside the Swing™ breastpump and provides the necessary a) time and b) vacuum parameters. By depressing the vacuum-adjust buttons, the microcontroller changes the vacuum and time parameters of the suction. The breast pump is capable of providing vacuum levels from 0 to 250mmHg, with cycling rates up to 130cpm. The program residing on the microcontroller is designed to deliver two pumping curves.

All materials with milk contact or components with human breast/skin 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 Medela® Swing™ 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 Medela® Swing™ 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 Medela® Swing™ breastpump is safe and effective for the intended use, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 2 2006

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

Re: K053052
Trade/Device Name: Swing™
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: April 13, 2006
Received: April 17, 2006

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K053052

Device Name: Swing™

Indications For Use:

The Swing™ breastpump is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

Prescription Use ✓ AND/OR Over-The-Counter Use X
(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053052