K041579

APR 2 1 2005

Section E - 510(k) Summary

Medela Obstetrical Vacuum Delivery System

1 Sponsor's Name, Address and Contact Person:

Sponsor:
Medela AG
Medical Equipment
Laettichstrasse 4b
6341 Baar
Switzerland
Phone: +41 41 769 5151 ext. 228
Fax: +41 41 769 5100

Contact Person
Werner Frei
Manager Regulatory Affairs

Date Summary Prepared: March 01 2004

2 Name of Device(s)

Trade Name: **Medela® Single Use Silc Cup**
Fetal Vacuum Extractor

Common Name: Obstetrical Vacuum Delivery System

Classification Name: Fetal Vacuum Extractor, Obstetrical and Gynecological Surgical
(Classified Class II, per 21 CFR Section § 884.4340).

3 Product Code

HDB

4 Name of the predicate Device(s)

Medela Inc.	OB Vacuum Extractor (K841492)
Hollister Inc.	Ameda/Egnell Dolphin Dispo-Soft Vacuum Extractor (K895700)

5 Description of Device

The **Medela® Single Use Silc Cup** is a sterile, disposable device made of an elastomer and available in one size, 60mm inner diameter. The instrument is made in one piece and consists of a handle and a suction cup to be used with an external vacuum pump and tubing.

The cup has a smooth external surface with a small longitudinal ridge, which makes it possible to observe any rotation. The inside of the cup is lined with small projections. The projections enable the air between the cup and the child's head to be evacuated and ensure that the cup sucks firmly against the child's head. The soft suction cup deforms, thereby ensuring optimal adhesion and minimizing trauma to the fetal scalp.

6 Intended Use of the Device

The Medela® Single Use Silc Cup is intended to be used to facilitate the delivery of the fetus during childbirth. The device enables traction to be applied to the fetal head (in the birth canal) by means of a suction cup attached to the scalp. It is powered by an external vacuum source and indicated for using during vaginal or cesarean delivery.

The Indications for use are

- Fetal distress in the second stage
- Maternal delay in the second stage
- Maternal conditions requiring a short second stage

Conditions for use of the Single Use Silc Cup

- Vertex presentation, with the head well-flexed
- Ruptured membranes
- Gestational age > 36 weeks
- Cervix fully dilated
- Head fully engaged abdominally

7 Summary of Technological Characteristics

The Technology of the **Medela® Single Use Silc Cup** is identical to the predicate devices and there are no technical differences which would raise new aspects regarding safety and effectiveness.

Based upon the information presented in section I - Biocompatibility, the materials used to fabricate the **Medela® Single Use Silc Cup** are considered as appropriate for their intended use.

8 Conclusion

Based upon the information presented above, it is concluded that the proposed **Medela® Single Use Silc Cup** 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

APR 2 1 2005

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

Re: K041579
Trade/Device Name: Medela® Single Use Silc Cup
Regulation Number: 21 CFR 884.4340
Regulation Name: Fetal vacuum extractor
Regulatory Class: II
Product Code: HDB
Dated: April 1, 2005
Received: April 6, 2005

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

510(k) Number (if known): K041579

Device Name: Medela® Single Use Silc Cup

Indications For Use:

- Fetal distress in the second stage
- Maternal delay in the second stage
- Maternal conditions requiring a short second stage

The Medela® Obstetrical Vacuum Delivery System (Single Use Silc Cup) is a sterile, disposable device intended to be used to facilitate the delivery of the fetus during childbirth. The device enables traction to be applied to the fetal head (in the birth canal) by means of a suction cup attached to the scalp. It is powered by an external vacuum source and indicated for using during vaginal or cesarean delivery.

Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041579