

4/26/99

K983776

## 510(k) Summary

**Submitter:** Evenflo Company, Inc.  
797 Crossroads Court  
Northwoods Business Center II  
Vandalia, Ohio 45377

Phone: (937) 415-3300 Fax: (937) 415-3112

**Contact Name:** Westly Hetrick

**Date Prepared:** October 9, 1998

**Common Name:** Breast Pump

**Trade Name:** Evenflo Comfort Control Breast Pump  
Evenflo Comfort Control Dual Breast Pump

**Classification Name:** Powered Breast Pump  
Class II Device - 21 C.F.R. § 884.5160

### Substantial Equivalence:

Evenflo Comfort Control Breast Pump and Comfort Control Dual Breast Pumps are substantially equivalent to the following currently marketed breast pumps:

<u>Company</u>	<u>Product Name</u>	<u>510(k) Clearance Number</u>
Medela, Inc.	Little Hearts Deluxe Battery Breast Pump	[Unknown]
Medela, Inc.	Mini-Electric Breast Pump	K901344
Medela, Inc.	Pump In Style	K950750
Ameda Egnell	Express and Premiere (Sold as: Purely Yours Breast Pump)	K973501

### General Description:

The Evenflo Comfort Control Adjustable Speed Breast Pump with Automatic Cycling, and the Evenflo Comfort Control Dual Adjustable Speed Breast Pump with Automatic Cycling are diaphragm type pumps, driven by small DC motors, that create cycling negative pressure. The negative pressure generated by the pump is sufficient to overcome the resistance to the outflow of milk that is created by the muscles, yet gentle enough to prevent tissue damage to the user. The cycling speed and the strength of the negative pressure are controlled by individual rotary controls located on the pump unit. The combination of cycling speed and negative pressure control allow for a range of pressures to be selected. When used as a single collection pump, the maximum negative pressure ranges from 173 mm Hg to 56 mm Hg, and when used in the dual mode, it ranges from 173 mm Hg to 43 mm Hg.

**Design and Materials:**

All food or human contact components are manufactured from material that meets FDA food additive criteria as set forth in 21 Code of Federal Regulations Parts 176, 177 and 178.

**Intended Use:**

The Evenflo Comfort Control Breast Pump and Comfort Control Dual Breast Pump are personal use battery/electric powered suction devices used to express milk from the breast of lactating women. These devices are not intended for hospital use.

**Technology Considerations:**

The following is a chart showing the similarities and difference between the Evenflo Comfort Control Breast Pump and Comfort Control Dual Breast Pump and its predicate devices:

	Evenflo Comfort Control	Medela Pump In Style	Ameda Egnell	Medela Little Hearts	Medela Mini Electric
Intended Use	To Express Milk	To Express Milk	To Express Milk	To Express Milk	To Express Milk
Power Source	AC Adapter or 2 C Batteries	AC Adapter	AC Adapter or 6 AA Batteries	AC Adapter or 2 D Batteries	AC Adapter or 2 AA Batteries
Single or Double Pumping	Yes	Yes	Yes	Single Only	Single Only
Adjustable Suction Levels	Yes	Yes	Yes	Yes	Yes
Adjustable Cycle Speed	Yes	No	Yes	No	No
Overflow Protection	Yes, valve in horn	Yes, reservoir type	Yes, reservoir type	Yes, non-woven fiber	No
Highest Vacuum Setting (in Hg)	6.8	7.3	6.7	6.5	6.8
Highest Vacuum Setting (mm Hg)	173	185	170	165	173
Lowest Vacuum Setting (in Hg)	1.7	3.7	1.2	3.7	4.3
Lowest Vacuum Setting (mm Hg)	43	94	30	94	109
Range of Cycle Speeds (Cycles/Minute)	54~36	49	60~29	33	31
Nipple Adapter	Yes	Yes	Yes	Yes	Yes
Time to 75% Initial Vacuum on Batteries (hours)	7	NA	1	20	3
Time to 0% Initial Vacuum on Batteries (hours)	10	NA	5	37	13

**Non-Clinical Testing:**

Evenflo conducted performance testing on its Comfort Control Pumps and each of the predicate devices. These tests measured the negative pressure generated by each pump and plotted the result as a function of time. Through these tests, a comparison of vacuum pressure and cycle speed could be determined. Tests were also conducted to determine the expected useful life of the battery for each pump.

**Conclusion:**

It is Evenflo Inc.'s conclusion that the Evenflo Comfort Control Breast Pump and Comfort Control Dual Breast Pump are substantially equivalent to its predicate devices. Based upon the test data submitted, the Comfort Control provides sufficient vacuum pressure to effectively express and collect milk from lactating women.



APR 26 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Donald E. Segal  
Akin, Gump, Strauss, Hauer & Feld  
1333 New Hampshire Avenue, NW  
Suite 400  
Washington, DC 20036Re: K983776  
Evenflo Comfort Control Dual Breast Pump  
Dated: April 15, 1999  
Received: April 15, 1999  
Regulatory Class: II  
21 CFR 884.5160/Procode: 85 HGX

Dear Mr. Segal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number: K983776

Device Name: Evenflo Comfort Control Breast Pump  
Evenflo Comfort Control Dual Breast Pump

Indications For Use: The Evenflo Comfort Control Breast Pump and Comfort Control Dual Breast Pump are personal use battery/electric powered suction devices used to express milk from the breast of lactating women. These devices are not intended for hospital use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segram  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K983776

Prescription Use \_\_\_\_\_ OR Over -The-Counter Use ✓

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)