evenflo
Evenflo Company, Inc.
707 Crossroads Court
Vandalia, Ohio 45377
(937) 415-3300

DEC 0 2 2002

K023933 page 1

510(K) PREMARKET NOTIFICATION
EVENFLO COMFORT SELECT AUTO-CYCLE BREAST PUMP KIT

1. Name of the Device

a. Proprietary Name - Evenflo Comfort Select Auto-cycle Breast Pump Kit

b. Classification Name - Powered Breast Pump

2. Intended Use

The Evenflo Comfort Select Auto-cycle Breast Pump Kit is an electrically operated suction device used to express milk from the breast.

3. Device Description

The Evenflo Comfort Select Auto-cycle Breast Pump is an electrically powered breast pump that uses the principle of negative suction to express milk from the breast. The Evenflo pump is sold in single and dual models. The dual model allows the user to pump one or both breasts at a time, and is designed with ergonomics in mind so as to be comfortable for the user. The single model applies the same ergonomics but is used to pump only one breast at a time. Evenflo believes its Comfort Select Auto-cycle Breast Pump is substantially equivalent to lawfully marketed breast pumps.

4. Establishment Registration Number

The Evenflo establishment registration number is 1519363.
The company address is:

Evenflo Company, Inc.
1000 Evenflo Dr.
P.O. Box 709
Canton, GA 30114

770-704-2000
Fax: 770-704-2002

5. Classification of the Device

21 CFR §884.5160 states that powered breast pumps are class II medical devices.

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6. Performance Standards for the Device

The Food and Drug Administration has established no performance standards for breast pumps.

7. Proposed Product Labeling

An initial copy of Evenflo Breast Pump product labeling is included in this notification (Appendix B).

8. Predicate Product(s)

The Evenflo Comfort Select Auto-cycle Breast Pump is substantially equivalent to the following powered breast pumps currently marketed:

Manufacturer	Breast Pump Trade Name
Medela	Double Pumping Mini-Electric
The First Years	Natural Comfort
Evenflo	Personal Comfort Dual Breast Pump

9. 510(k) statement

Evenflo's 510(k) statement is attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 2 2002

Mr. Matthew G. McCarty
Product Safety Engineer
Evenflo Company, Inc.
707 Crossroads Court
VANDALIA OH 45377

Re: K022933
Trade/Device Name: Evenflo Comfort Select Auto-Cycle Breast Pump kit
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: 85 HGX
Dated: August 30, 2002
Received: September 4, 2002

Dear Mr. McCarty:

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 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:

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" (21 CFR Part 807.97). 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): K022933

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

Indications for Use: The Evenflo Comfort Select Breast Pump and Comfort Select Dual Breast Pump are personal use battery/electric powered suction device used to express milk from the breast of lactating women.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Edward C. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal, [illegible]
and Radiological Devices
510(k) Number K022933

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