K131153

510(k) Summary

JUN 18 2013

Date of Preparation: 17-Jun-2013

Evenflo Feeding, Inc.
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West Chester, OH 45069

Tel – 513-870-1629
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Official Contact: Mr. Wade Halma
Product Integrity Engineering Manager

Proprietary or Trade Name: Evenflo Advanced Double Electric Breast Pump

Common/Usual Name: Powered breast pump

Classification Name: Powered breast pump
HGX - CFR 884.5160
Class 2 - OTC

Predicate Devices: K973501 – Ameda – Purely Yours
K102600 – Evenflo – SimplyGo

Device Description:
The Evenflo Advanced Double Electric Breast Pump is an electrically powered breast pump that uses negative pressure to express milk from a lactating woman's breasts. A reciprocating vacuum pump, driven by a microprocessor, generates the suction to extract the milk at vacuum levels between 25 and 254 mmHg. The flange system is convertible between single and double pumping.

Four buttons on the user interface allow the user to select one of 32 settings (eight vacuum levels and four cycle rates for each vacuum level) and the LED interface displays the selected setting. Additionally, there are three different flange sizes that allow the user to select the size that best fits their breasts. These features allow the user to customize the device, improving the comfort of their pumping experience.

The device can be powered by six "AA" batteries or the provided mains adapter.

Indications for Use:
The Evenflo Advanced Double Electric Breast Pump is an electrically powered suction device intended to express and collect milk from lactating woman's breasts. This is for a single user.

Patient Population: Lactating women

Environment of use: Home

Contraindications: None

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Attribute	New device Advanced Double Electrical Breast Pump	Ameda Purely Yours K973501	EvenFlo SimplyGo K102600
Intended Use	Express milk	Express milk	Express milk
Patient population	Lactating women	Lactating women	Lactating women
Environment of use	Home	Home	Home
OTC	Yes	Yes	Yes
Power Source	AC / Battery	AC / Battery	AC / Battery
Pump Style	Reciprocating Vacuum Pump	Single-Stroke Reciprocating Vacuum Pump	Reciprocating Vacuum Pump
Single/double Pumping	Both	Both	Single
Adjustable Suction Levels	Yes	Yes	Yes
Cycle Speed	30 – 80	30 - 60	46 (fixed)
Overflow Protection	Yes (diaphragm)	Yes (diaphragm)	Yes (float)
Vacuum range - double (mmHg)	25-254	75-200	N/A
Vacuum range - single (mmHg)	25-270	75-270	3-254
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Mechanical cycling with suction regulator
Accessories **Flanges and Inserts come in multiple sizes**	Flange Soft Flange Bottle Tubing Check valve Diaphragm	Flange Soft Flange Bottle Tubing Check valve Diaphragm	Flange (horn) Soft Flange (horn insert) Bottle Check valve Overflow Valve
Software	Yes	Yes	No
Cleaning method for Accessories	Boiling water	Boiling water	Boiling water
Materials	Identical to Predicate K102600	N/A	ISO 10993 Compliant
Electrical Safety	UL 1431	UL 1431	UL 1431

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The Evenflo Advanced Double Electric Breast Pump is viewed as substantially equivalent to the predicate devices because:

Indications –

- Indications for use are to express milk of lactating women. This is for a single user.

Discussion – Indications for Use statements between the subject device and the predicate device are not identical, but the intended use of the three devices—to express milk from the breasts of lactating women—is the same.

Technology –

- The technology of a reciprocating vacuum pump to express milk and the flange and collection bottle system are identical to the predicate. The power source, user controls, ability to adjust vacuum and frequency settings and performance specifications are identical to the predicates.

Discussion – The technology and principle of operation for the proposed device is identical to the predicates - Evenflo SimplyGo – K102600 and the Ameda Purely Yours – K973501.

Materials –

- The materials which are in contact with the user and the expressed milk are identical to the predicate.

Discussion – The materials are identical to the predicate - Evenflo SimplyGo – K102600.

Environment of Use –

- The environment of use, home, is identical to the predicates.

Discussion – The environment of use is identical to the predicates - Evenflo SimplyGo – K102600 and the Ameda Purely Yours – K973501.

Patient Population –

- The patient population is lactating women which is identical to the predicates.

Discussion – The user population is identical to the predicates - Evenflo SimplyGo – K102600 and the Ameda Purely Yours – K973501.

Non-clinical Testing Summary -

We have performed a number of bench tests to demonstrate the Evenflo Advanced Dual Electric Breast Pump performs within its specifications and within the performance specification ranges of the predicate devices. These tests included:

- Vacuum testing
- General Electrical Safety – UL 1431, FCC 15A, CISPR 11:2009
- Sound Pressure
- Operational Forces to assemble and disassemble components
- Check Valve
- Battery Life

In addition, we performed comparative vacuum and cycle testing with the proposed device and the predicates. It was demonstrated that the proposed device is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2013

Evenflo Feeding, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131153
Trade/Device Name: Evenflo Advanced Double Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: May 26, 2013
Received: June 4, 2013

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K131153

Device Name: Evenflo Advanced Double Electric Breast Pump

Indications for Use:

The Evenflo Advanced Double Electric Breast Pump is an electrically powered suction device intended to express and collect milk from a lactating woman's breasts. This is for a single user.

Prescription Use (Part 21 CFR 801 Subpart D)	**or**	**Over-the-counter use XX** (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)

Herbert P. Lerner -S

K131153