

510(k) Summary
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12-Feb-2010

K100435

MAY 28 2010

Evenflo Company, Inc.
225 Byers Road
Miamisburg, OH 45342

Tel – (937) 415-3215
Fax – (937) 859-7561

Official Contact: Amy Neff – Associate General Counsel

Proprietary or Trade Name: Ameda Platinum Breast Pump

Common/Usual Name: Powered breast pump

Classification Name: Powered breast pump
HGX - CFR 884.5760

Predicate Devices:
K020518 – Medela Symphony
K950531 – Ameda Elite breast pump
K052909 – Evenflo Elan breast pump
K011519 – Ameda HygieniKit

Device Description:

The Ameda Platinum electric breast pump is a simple and effective system for expressing milk from a mother's lactating breast(s). The Ameda Platinum Breast Pump is electric or battery operated. The Ameda Platinum Breast Pump utilizes the separately supplied predicate device, the Ameda HygieniKit.

Indications for Use:

The Ameda Platinum Breast Pump is intended to express and collect milk from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs.

Patient Population: Lactating women

Environment of use: Hospitals, institutions and home

Contraindications: None

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Attribute	Ameda Platinum
Intended Use	Express milk
Patient population	Lactating women
Environment of use	Hospital, institutions and home
Power Source	AC Battery
Pump Style	Piston
Single/double Pumping	Both
Adjustable Suction Levels	Yes
Cycle Speed	30 – 80
Overflow Protection	No
Vacuum range – (mmHg)	30 – 250
Uses HygieneKit	Yes
Software	Yes

The Ameda Platinum breast pump is viewed as substantially equivalent to the predicate devices because:

Indications –

Similar to predicates – Medela Symphony (K020518) breast pump and Ameda Elite (K950531) and Evenflo Elan (K052909) breast pumps

Technology –

Similar to predicates – Ameda Elite (K950531) and Evenflo Elan (K052909) breast pumps

Materials –

Materials in contact with the user and expressed milk are identical to predicate – Ameda HygieneKit (K011519)

Environment of Use –

Identical to predicates – Medela Symphony (K020518) breast pump and Ameda Elite (K950531) and Evenflo Elan (K052909) breast pumps

Patient Population –

Identical to predicates – Medela Symphony (K020518) breast pump and Ameda Elite (K950531) and Evenflo Elan (K052909) breast pumps

Performance Testing and Differences

We have performed bench tests to demonstrate the Ameda Platinum breast pump performs within its specifications, included vacuum and life cycling. There are no differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY 28 2010

Mr. Steve Nowak
Engineering Manager, Ameda Breastfeeding products
Evenflo Company, Inc.
225 Byers Road
MIAMISBURG OH 45342

Re: K100435
Trade/Device Name: Ameda Platinum Breast Pump
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered breast pumps
Regulatory Class: II
Product Code: HGX
Dated: April 29, 2010
Received: April 30, 2010

Dear Mr. Nowak:

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.

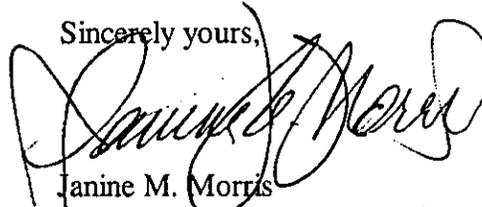
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K100435 (To be assigned)

Device Name: Ameda Platinum Breast Pump

Indications for Use:

The Ameda Platinum Breast Pump is intended to express and collect milk from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs.

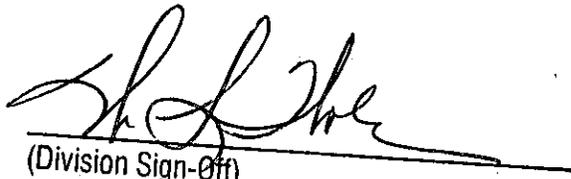
Prescription Use
(Part 21 CFR 801 Subpart D)

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)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

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