AUG 15 2006

Playtex Products, Inc.

K061013

Technical Center
75 Commerce Drive
Allendale, New Jersey 07401-1600
201 785-8000

510(k) Summary of Safety and Effectiveness
March 27, 2006

Submitter: Playtex Products, Inc.
75 Commerce Drive
Allendale, NJ 07401
Phone: 201-785-8000

Contact Name: Karin Jordan
Senior Regulatory Affairs and Compliance Manager

Trade name: Playtex Embrace Petite Double Electric Breast Pump

Common name: Powered Breast Pump for Mother's Milk

Classification name: Powered Breast Pump, 21 CFR 884.5160 (85 HGX) Class II

Substantial Equivalence: Playtex Breast Pump is substantially equivalent to the following currently marketed breast pumps:

Company	Product Name	510(k) Clearance Number
Playtex Products, Inc.	Embrace	K022594
Ameda Egnell	Elite	K950531
Medela	Pump-in-Style,	K950750

General Description:

The Playtex electric breast pump is a small, quiet, safe and effective system for expressing milk from a lactating mother's breast(s). This device is comprised of 3 major assemblies: a pump assembly, a breast cup assembly, and some commercially available items (i.e., bottles, bottle liners, etc). The device is designed with 1 pre-set speed level and 3 pre-set suction settings, which are selectable by the user via a rotating dial. The device is powered by a 12V DC power supply, which is included with the package.

K061013

Design and Materials:

All milk and human contact components are manufactured from materials that meets FDA food additive criteria as set forth in Part 21 Code of Federal Regulations Parts 176, 177 and 178. In addition, the silicone breast cup insert has been tested for biocompatibility per established guidelines. These items have been previously approved under 510(k) #K022594.

Intended Use:

The intended use of the Playtex Embrace Petite Breast Pump is to express milk from the breast of lactating women.

Comparison to Predicate Devices

The following is a chart showing the similarities and differences between the Playtex Breast Pump and the Predicate Devices:

	Playtex Embrace Petite Breast Pump	Playtex Embrace Breast Pump	Medela Pump-in-Style	Ameda Purely Yours
510(k) Number	N/A	K022594	K950750	K973501
Intended Use	To Express Milk	To Express Milk	To Express Milk	To Express Milk
Power Source	DC Power Supply	DC Power Supply	DC Power Supply	DC Power Supply or 6 AA Batteries
Pump Type	Reciprocating Piston	Reciprocating Piston	Reciprocating Diaphragm	Reciprocating Piston
Single or Double Pumping	Both	Both	Both	Both
Adjustable Suction Levels	Yes	Yes	Yes	Yes
Adjustable Cycle Speed	No	Yes	Yes	Yes
Overflow Protection	Yes	Yes	No	Yes
Highest Vacuum Setting (in Hg)	8.4	9.0	7.2	6.4
Lowest Vacuum Setting (in Hg)	2.8	3.1	3.8	0.8
Range of Cycle Speeds (Cycles/min)	45	57-40	66-41	67– 29
Breast Cup-to-Breast Interface	Soft Silicone	Soft Silicone	Rigid Plastic	Rigid Plastic (partial silicone covering avail.)
Active Breast Massage	Yes	Yes	No	No

Discussion of Non-Clinical Tests:

Testing of the device has demonstrated that the Playtex breast pump meets established requirements when used in the manner and environment specified in product labeling.

K061013

Discussion of Clinical Tests Performed:

No clinical tests have been conducted on this device.

Conclusion:

In conclusion, the Playtex Embrace Petite Breast Pump is substantially equivalent to its predicate devices. Based upon the test data submitted, the device provides sufficient vacuum pressure to effectively and safely express and collect milk from lactating women.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 15 2006

Ms. Karin E. Jordan
Senior Regulatory Affairs and Compliance Manager
Playtex Products, Inc.
75 Commerce Drive
ALLENDALE NJ 07401

Re: K061013
Trade/Device Name: Playtex® Petite Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: July 6, 2006
Received: July 7, 2006

Dear Ms. Jordan:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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

Indications for Use Statement

Applicant: Playtex Products, Inc.

510(k) Number (if known): K061013

Device Name: Playtex® Petite Breast Pump

Indications for Use: An electrically powered breast pump used to express milk from the breast of a lactating woman.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

or (Over-the-Counter Use)

(Optional format 1-26-99)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061013

PROPRIETARY DATA: This document and information contained herein may not be reproduced, used or disclosed without written permission of Playtex Products, Inc.