Playtex Products, Inc.

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

**510(k) Summary of Safety and Effectiveness**
July 9, 2002

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

**Contact Name:** Dr. Paul A. Siracusa
Senior Vice President, Research & Development

**Trade name:** Playtex 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 |
|---|---|---|
| Ameda Egnell | Express and Premier | K973501 |
| 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 4 major assemblies: a pump assembly, a breast cup assembly, a carry bag, and some commercially available items (i.e., bottles, bottle liners, etc). The device is designed with 5 pre-set suction levels and 5 pre-set speed settings, which are selectable by the user via a button pad. The device is powered by a 12V DC power supply, which is included with the package.

## 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.

## Intended Use:

The intended use of the Playtex 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 Breast Pump | Medela Pump-in-Style | Ameda Purely Yours | Ameda Elite |
|---|---|---|---|---|
| **510(k) Number** | N/A | K950750 | K973501 | K950531 |
| **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 or 6 AA Bateries | DC Power Supply |
| **Pump Type** | Reciprocating Piston | Reciprocating Diaphragm | Reciprocating Piston | Reciprocating Piston |
| **Single or Double Pumping** | Both | Both | Both | Both |
| **Adjustable Suction Levels** | Yes | Yes | Yes | Yes |
| **Adjustable Cycle Speed** | Yes | No | Yes | Yes |
| **Overflow Protection** | Yes | No | Yes | Yes |
| **Highest Vacuum Setting (in Hg)** | 9.0 | 7.3 | 6.7 | 9.8 |
| **Lowest Vacuum Setting (in Hg)** | 2.5 | 3.7 | 1.2 | 0.0 |
| **Range of Cycle Speeds (Cycles/min)** | 75 - 45 | 49 | 60 – 29 | 60 – 30 |
| **Breast Cup-to-Breast Interface** | Soft Silicone | Rigid Plastic | Rigid Plastic (partial silicone covering avail.) | Rigid Plastic |
| **Active Breast Massage** | Yes | No | No | No |
| **Hospital Grade System** | Yes | No | Yes | Yes |
| **Usable on Tabletop or Inside Bag** | Both | Inside | Tabletop | Tabletop |

**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.

**Discussion of Clinical Tests Performed:**

No clinical tests have been conducted on this device.

**Conclusion:**

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

Paul A. Siracusa, D. En. Sc.
Senior Vice President
Research and Development
Playtex Products, Inc.
75 Commerce Drive
ALLENDALE NJ 07401

Re: K022594
Trade/Device Name: Playtex Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: 85 HGX
Dated: July 26, 2002
Received: August 5, 2002

Dear Dr. Siracusa:

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

## Indications for Use Statement



Applicant: Playtex Products, Inc.

510(k) Number (if known): K022594

Device Name: Playtex® 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 _____ or ( Over-the-Counter Use
(Per 21 CFR 801.109)

(Optional format 1-26-99)

David A. Lepman

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K022594