K032636

NOV 14 2003

510(k) SUMMARY

Name of 510(k) Sponsor:	Playtex Products, Inc.
Address:	75 Commerce Drive Allendale, New Jersey 07401
Telephone: Fax:	(201) 785-8090 (201) 785-8212
Contact Person:	Karen A. Costa, Ph.D. Director, Regulatory, Safety & Biomedical Affairs
Date of Summary:	August 25, 2003
Proprietary Name of Device:	Playtex Tampons **#13203** & **#13203PV**
Generic/Classification Name:	Unscented menstrual tampon

Legally Marketed Predicate Devices:

Playtex ***SilkGlide***® Odor-Absorbing Cardboard Applicator Tampons (K981760).

Device Description and Technological Characteristics:

Unscented menstrual tampons for the absorption of menstrual fluid. The new tampon has the same technological characteristics as the predicate device. The fiber, string and materials in contact with the vaginal wall are the same or have the same mode of action.

Intended Use:

Playtex tampons are intended to be used as unscented menstrual tampons for the absorption of menstrual fluid.

Testing:

Clinical and nonclinical testing conducted included sensitization, irritation, acute oral toxicity, subacute vaginal irritation, agar diffusion and TSST-1 toxin testing. Based on these data, it can be concluded that the Playtex **#13203** and **#13203PV** tampons are substantially equivalent to the predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Karen A. Costa, Ph.D.
Director, Regulatory &
Biomedical Affairs
Playtex Products, Inc.
Technical Center
75 Commerce Dr.
ALLENDALE NJ 07401-1600

Re: K032636
Trade/Device Name: Playtex® Unscented Cardboard Applicator Tampon #13203(colored) and #13203PV(non-colored)
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HEB
Dated: August 25, 2003
Received: August 28, 2003

Dear Dr. Costa:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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): K032636

Device Name: Playtex® Unscented Cardboard Applicator **Tampon #13203** (colored) and **#13203PV** (non-colored)

Indications for Use: unscented tampons for the absorption of menstrual fluid

(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)

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

510(k) Number K032636