

K060981

## 510(k) SUMMARY

Name of 510(k) sponsor: Playtex Products, Inc.

Address: 75 Commerce Drive  
Allendale, NJ 07401-1600  
Telephone: 201.785.8101  
Facsimile: 201.785.8242

Contact information: Mr. Keith Edgett  
Playtex Products, Inc.  
Telephone: 302.678.6880  
Facsimile: 302.678.6540

Date summary prepared: April 7, 2006

Proprietary name of device: Playtex Sport Plastic, Playtex Sport Plastic Multipack  
Tampons

Generic/classification name: Scented and Unscented Menstrual Tampons

Product code (classification): Scented or scented deodorized menstrual tampons and  
unscented menstrual tampons are Class II medical devices  
(HIL, 21 C.F.R. § 884.5460 and HEB, § 884.5470,  
respectively).

### Legally Marketed (Unmodified) Devices:

Playtex Non-deodorant & Deodorant Gentle Glide  
Playtex Non-deodorant & Deodorant Gentle Glide Multipack Tampons

K830966, K020201, K912002

### Device Description:

Scented or scented deodorized, unscented menstrual tampons for the absorption of menstrual fluid.

### Intended Use:

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

**Technological Characteristics:**

The new tampon has the same technological characteristics as the cleared tampon. The fiber, string, and materials in contact with the vaginal wall are the same or have the same mode of action. The only differences in the modified tampons from the predicate devices are: the composition of the colorants incorporated into the polyethylene resin used to manufacture the applicator barrel and plunger; a new fragrance; and the contoured shape of the applicator and pledget.

**Performance Data:**

Cytotoxicity testing, acute systemic toxicity testing, vaginal irritation testing, dermal irritation, allergic contact sensitization tests, microbial agar diffusion and toxic shock syndrome toxin-1 (TSST-1) testing indicate that the modified device meets all device input requirements.

**Conclusions:**

The modified Playtex tampons are substantially equivalent to the predicate tampons.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

MAY - 9 2006

Mr. Keith Edgett  
Vice President  
Playtex Products, Inc.  
75 Commerce Drive  
ALLENDALE NJ 07401

Re: K060981

Trade/Device Name: Playtex Sport Plastic Tampons, Unscented and Playtex Sport Plastic Tampons,  
Fresh Scent

Regulation Number: 21 CFR 884.5460

Regulation Name: Scented or scented deodorized menstrual tampon

Regulatory Class: II

Product Code: HIL

Dated: April 7, 2006

Received: April 11, 2006

Dear Mr. Edgett:

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.



*Protecting and Promoting Public Health*

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.

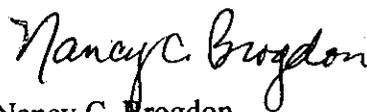
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



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

K060981

510(k) Number (if known): Playtex Products, Inc.  
 Device Name: Playtex Sport Plastic Tampons, unscented  
 Playtex Sport Plastic Tampons, fresh scent  
 Indications For Use: Playtex Sport Plastic Tampons  
 (unscented/fresh scent) for the  
 absorption of menstrual fluid.

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use   
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K060981