K073662

510(k) SUMMARY

Name of 510(k) sponsor:	Playtex Products, Inc.
Address:	Playtex Products, Inc. 804 Walker Rd. Dover, DE 19904 Telephone: 302.678.6880 Facsimile: 302.678.6540
Contact information:	Mr. Keith Edgett Vice President Research and Development Playtex Products, Inc. Telephone: 302.678.6880 Facsimile: 302.678.6540
Date summary prepared	December 21, 2007
Proprietary name of device:	Playtex Gentle Glide, Playtex Gentle Glide 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).

JAN 17 2008

Legally Marketed (Unmodified) Devices:

Playtex Non-deodorant & Deodorant Gentle Glide (K961870)
Playtex Non-deodorant & Deodorant Gentle Glide Multipack Tampons (K070745)

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 tampon from the predicate devices are the absorbency (lower), the dimensions of the unformed pledget pads, and the dimensions of the final formed pledget.

Performance Data:

Cytotoxicity testing, acute systemic toxicity testing, vaginal irritation testing, 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 tampon is substantially equivalent to the predicate tampons.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2008

Mr. Keith Edgett
Vice President, Research and Development
Playtex Products, Inc.
804 Walker Rd.
DOVER DE 19904

Re: K073662
Trade/Device Name: Playtex Gentle Glide and Playtex Multipack Tampons
Regulation Number: 21 CFR 884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulatory Class: II
Product Code: HIL and HEB
Dated: December 21, 2007
Received: December 26, 2007

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 (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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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: K073662

Device Name: Playtex Gentle Glide and Playtex Gentle Glide Multipack Tampons

Indications for Use: Scented or scented deodorized menstrual tampon for the absorption of menstrual fluid; unscented menstrual tampon for the absorption of menstrual fluid.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ or Over-the Counter Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073662