K072376

DEC 1 2 2007

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:	July 24, 2007
Proprietary name of device:	Playtex Gentle Glide, Playtex Gentle Glide Multipack Tampons (Ultra Absorbency)
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

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 ultra absorbency tampon has the same technological characteristics as the cleared tampon. The fiber; string; colorants incorporated into the polyethylene resin used to manufacture the applicator barrel and plunger; deodorizing scent; and materials in contact with the vaginal wall are the same or have the same mode of action. The only differences between the Playtex Gentle Glide Tampons and the predicate devices listed above are: the absorbency level, wavy band – flared finger grip design, rolled end plunger design, applicator dimensions, the dimensions of the rayon cross-pads used to form the pledget, and the dimensions of the final formed pledget.

Biocompatibility and 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), and a clinical study [double-blind, randomized, comparative in-use evaluation of tampon products for overall safety and effect on the vaginal micro flora] testing indicate that the modified device meets all device input requirements.

Syngyna Absorbency Results

The new scented and unscented tampons are in compliance with the requirements for Ultra absorbency as set forth in 21 C.F.R. § 801.430(e)(1), "User Labeling for Menstrual Tampons."

Conclusions:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2007

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

Re: K072376
Trade Name: Playtex Gentle Glide and Playtex Gentle Glide Multipack Tampons
Regulation Number: 21 CFR §884.5460
Regulation Name: Scented menstrual tampon
Regulatory Class: II
Product Code: HIL and HEB
Dated: October 31, 2007
Received: November 2, 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

Indications for Use

510(k) Number (if known): K072376

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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072376