JUN 21 2012 K120245

510(k) Summary

Name of 510(k) Sponsor	Playtex Products, LLC 6 Research Drive Shelton, CT 06484
Contact Information	Pushpa Rao, Ph.D., D.A.B.T., R.A.C. Senior Manager, Product Safety/North American Regulatory Affairs Research & Development Playtex Products, LLC 75 Commerce Drive Allendale, NJ 07401 Telephone: 201-785-8070 Facsimile: 201-785-8202
Summary prepared on	January 25, 2012
Pre-Market Notification #	
Reason for Submission	Changes to the applicator colorant, fragrance and pledget design compared to predicate tampons. Pre-clinical and clinical testing confirmed that these changes did not affect the safety of the modified tampon. These changes were not expected to affect efficacy, and this was verified by performance testing. The results of these tests are included in this 510(k) pre-market notification.
Name of Device Trade Name	Playtex® Gentle Glide Scented Tampons Playtex® Gentle Glide Unscented Tampons
Common Name	Menstrual Tampon, Scented and Unscented
Classification Name	Tampon, Menstrual Scented and Unscented
Classification Code	HIL, HEB
Predicate Devices	Playtex® Gentle Glide and Playtex® Gentle Glide Multipack Tampons (K073662) Playtex® Gentle Glide Plastic and Playtex® Gentle Glide Plastic Multipack Tampons (K070745) Playtex® Non-deodorant Gentle Glide (unscented), Playtex Deodorant Gentle Glide (Scented) and Playtex Non-deodorant and Deodorant Multipack Tampons (K072376)
Device Description	Scented or scented deodorized, unscented menstrual tampons for the absorption of menstrual fluid.
Intended Use	Playtex scented or scented deodorized menstrual tampons are intended to be inserted into the vagina and used to absorb menstrual fluid; Playtex

	unscented menstrual tampons are inserted into the vagina and used to absorb menstrual fluid.
Technological Characteristics	The modified tampons have the same technological characteristics as the predicate devices (K070745, K072376 and K073662). The fiber 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 tampons are: (1) the composition of the colorants incorporated into the polyethylene resin used to manufacture the applicator (barrel and plunger); (2) a new fragrance; (3) a new pledget design.
Biocompatibility Tests	Biocompatibility and microbiological studies of the modified tampons were conducted in accordance with the FDA guidance and applicable standards. The results demonstrate that the modified Playtex Gentle Glide tampons are safe and effective for their intended use and are substantially equivalent to legally marketed predicate tampons. The testing included: <u>Preclinical</u>: Cytotoxicity Vaginal Irritation in Rabbits Acute Systemic Toxicity Zone of Inhibition (Vaginal Microflora) Toxic Shock Syndrome Test *In vitro* Vaginal Irritation <u>Clinical</u> Human Repeat Insult Patch Test (Sensitization) Human Vaginal Irritation (Safety In Use)
Performance Testing	Syngyna testing was conducted in accordance to 21 CFR §801.430(f)(2) to verify that the modified tampons met absorbency ranges as specified in the regulation. • Absorbs menstrual flow < 6 grams (Slender Light) • Absorbs menstrual flow 6-9 grams (Slender Regular, Regular) • Absorbs menstrual flow 9-12 grams (Super) • Absorbs menstrual flow 12-15 grams (Super Plus) • Absorbs menstrual flow 15-18 grams (Ultra) The tampons are labeled in accordance to these absorbency ranges.
Conclusion	The results of the preclinical and clinical testing indicate that the modified tampons are safe and effective for their intended use and when considered in conjunction with the performance testing results are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2012

Pushpa Rao, Ph.D., D.A.B.T, R.A.C.
Senior Manager, Product Safety/North American Regulatory Affairs
Playtex, Inc.
75 Commerce Drive
ALLENDALE NJ 07401

Re: K120245
Trade/Device Name: Playtex® Gentle Glide Scented & Unscented Tampons
Regulation Number: 21 CFR§ 884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulatory Class: II
Product Code: HIL, HEB
Dated: June 11, 2012
Received: June 12, 2012

Dear Dr. Rao:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Playtex® Gentle Glide Scented Tampons

Playtex® Gentle Glide Unscented Tampons

Indications For Use:

Playtex® Gentle Glide Scented menstrual tampons are intended to be inserted into the vagina and used to absorb menstrual fluid.
Playtex® Gentle Glide Unscented menstrual tampons are intended to be inserted into the vagina and used to absorb menstrual fluid.

Absorbency Ranges:	Absorbs menstrual flow < 6 grams (Slender Light)
	Absorbs menstrual flow 6-9 grams (Slender Regular, Regular)
	Absorbs menstrual flow 9-12 grams (Super)
	Absorbs menstrual flow 12-15 grams (Super Plus)
	Absorbs menstrual flow 15-18 grams (Ultra)

Prescription Use _____ AND/OR Over-The-Counter Use__X__
(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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120245