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/Regulatory Affairs Research & Development Playtex Products, LLC 75 Commerce Drive Allendale, NJ 07401 Telephone: 201-785-8070 Facsimile: 201-785-8202
Date Submitted:	June 15, 2011
Submission #:	K111684
Reason for Submission:	The submission was filed to clear changes to the tampon treatment to include the OdorShield™ technology and show substantial equivalence of the subject tampon to the predicate devices.
Name of Device Trade Name	Playtex Sport (Unscented) Tampons with OdorShield™; Playtex Sport (Scented) Tampons with OdorShield™
Common Name	Menstrual Tampon, Scented and Unscented Tampon, Menstrual Scented and Unscented
Classification Name	Tampon
Regulation Number	§ 884.5460 § 884.5470
Product Code	HIL, HEB
Predicate Devices	Playtex® Non-deodorant Sport (unscented), Playtex Deodorant Sport (fresh scent) Tampons (K060981) Playtex Gentle Glide Tampons (K070745)
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 intended to be inserted into the vagina and used to absorb menstrual fluid.
Technological Characteristics	The new tampon has the same technological characteristics as the predicate device (K060981). The fiber, string and materials in contact with the vaginal wall are the same or have the same mode of action. The only difference is the modified use of the odor absorbing technology which is already used in the currently marketed Playtex Gentle Glide devices (K070745).
Biocompatibility Tests	Biocompatibility and microbiological studies were conducted in accordance with the FDA guidance and applicable standards on the subject tampons. The testing included: Cytotoxicity – ISO Agar Overlay Sensitization – Human Repeat Insult Patch Test Irritation – Human Vaginal Irritation Study Acute Systemic Toxicity – Human Vaginal Irritation Study The test articles, polar and non-polar extracts of the subject tampons were evaluated for sensitization potential under occlusion using, a nine patch induction phase over a period of three weeks, two week rest and challenge; The response to challenge was monitored post patch over a 72 hour period. Both scented and unscented tampons were provided to a panel of women of appropriate age over 2 menstrual cycles in randomized double-blind study. Expert assessments were made at baseline, midpoint and termination of study by colposcopy.
Microbiology Tests	Zone of Inhibition TSST-1 Testing
Odor Absorption Testing	Testing included expert panel assessment on OdorShield™ Technology and later validated in consumer testing.
Syngyna Testing:	Syngyna testing was conducted in accordance to 21 CFR 801.430(f)(2) to verify that the subject tampons met absorbency ranges as specified in the regulation. • Absorbs menstrual flow 6-9 grams (Regular) • Absorbs menstrual flow 9-12 grams (Super) • Absorbs menstrual flow 12-15 grams (Super Plus) The tampons are labeled in accordance to these ranges.
Conclusion	Results of performance testing indicate that the subject tampon is 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

Pushpa Rao, Ph.D.
Global Manager Product Safety/Regulatory Affairs
Playtex Manufacturing Inc.
75 Commerce Drive
ALLENDALE NJ 07401

FEB - 3 2012

Re: K111684
Trade/Device Name: Playtex Sport (Scented) with OdorShield™
Regulation Number: 21 CFR§ 884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulatory Class: II
Product Code: HIL
Dated: January 26, 2012
Received: January 27, 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): K111684

Device Name:

Playtex Sport (Unscented) with OdorShield™

Indications for Use:

Playtex Unscented deodorized menstrual tampon are intended to be inserted into the vagina and used to absorb menstrual fluid.

Absorbency Ranges:	Absorbs menstrual flow 6-9 grams (Regular)
	Absorbs menstrual flow 9-12 grams (Super)
	Absorbs menstrual flow 12-15 grams (Super Plus)

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

(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, Gastro-Renal, and Urological Devices

CONFIDENTIAL 510(k) Number K111684

Indications for Use

510(k) Number (if known): K111684

Device Name:

Playtex Sport (Scented) with OdorShield™

Indications for Use:

Playtex Scented or scented deodorized menstrual tampon are intended to be inserted into the vagina and used to absorb menstrual fluid.

Absorbency Ranges:	Absorbs menstrual flow 6-9 grams (Regular)
	Absorbs menstrual flow 9-12 grams (Super)

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 OF NEEDED)

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