K022882

510(k) SUMMARY

SEP 16 2002

Name of 510(k) sponsor:	Playtex Products, Inc.
Address:	75 Commerce Drive Allendale, NJ 07401-1600 Telephone: 201.785.8100 Facsimile: 201.785.8242
Contact information:	Dr. Paul A. Siracusa Telephone: 201.785.8101 Facsimile: 201.785.8242
Date summary prepared:	August 28, 2002
Proprietary name of device:	Playtex Gentle Glide®, Playtex Portables®, Playtex Gentle Glide® Multipack, and Playtex Slimfits® 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 & Odor-absorbing Gentle Glide®
Playtex Non-deodorant & Deodorant Portables®
Playtex Non-deodorant & Deodorant Slimfits®
Playtex Non-deodorant & Deodorant Gentle Glide® Multipack Tampons

K020200–K020202; K993794; K961870; K830966

Device Description:

Scented, Unscented menstrual tampons for the absorption of menstrual fluid.

Intended Use:

Playtex tampons are intended to be used as scented, 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 difference in the modified tampons from the cleared devices listed above is the composition of the colorants incorporated into the polyethylene resin used to manufacture the applicator barrel and plunger.

Performance Data:

Human sensitization, dermal irritation, acute oral toxicity, subacute vaginal irritation, cytotoxicity, extraction, and TSST-1 toxin 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2002

Paul A. Siracusa, D. En. Sc.
Senior Vice President,
Research & Development
Playtex Products, Inc.
Technical Center, 75 Commerce Dr.
ALLENDALE NJ 07401-1600

Re: K022882
Trade/Device Name: Playtex Non-Deodorant, Deodorant & Odor-absorbing Gentle Glide®: Non-Deodorant & Deodorant Portables®: Slimfits®: Gentle Glide® Multipack Tampons
Regulation Number: 21 CFR 884.5460
Regulation Name: Scented or scented deodorized Menstrual tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HIL and HEB
Dated: August 29, 2002
Received: August 30, 2002

Dear Mr. Siracusa:

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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: K022882

Device Name: Playtex Non-deodorant, Deodorant and Odor-absorbing Gentle Glide®, Playtex Non-deodorant and Deodorant Portables®, Playtex Non-deodorant and Deodorant Slimfits®, and Playtex Non-deodorant and Deodorant Gentle Glide® Multipack Tampons (#24002)

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 ✓

David G. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022882