AUG 1 9 1998

K982383

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9. 510(k) SUMMARY

A. SUMMARY OF SAFETY AND EFFECTIVENESS

1. COMPANY NAME - Playtex Products Inc.

ADDRESS - 215 College Road
P. O. Box 728
Paramus, New Jersey 07652

TELEPHONE - 201-265-8000

CONTACT PERSON - M. Rosengarten
Director of Regulatory & Biomedical Affairs

DATE OF SUMMARY - July 7, 1998

2. DEVICE NAME - Playtex Tampons

CLASSIFICATION NAME - Unscented Menstrual Tampons

3. The new Playtex tampons are substantially equivalent to previously cleared Playtex Gentle Glide®, Slimfits™ and Soft Comfort™ Tampons, Regular, Super and Super Plus.

4. The device description is: Scented or scented deodorant and unscented menstrual tampons for the absorption of menstrual fluid.

5. Playtex tampons are intended to be used as scented, scented deodorant and unscented menstrual tampons for the absorption of menstrual fluid.

6. The new tampon has the same technological characteristics as the predicate device and has the same mode of action. The fiber, string and materials in contact with the vaginal wall are the same or have the same mode of action.

B. 1. Nonclinical testing referenced for the determination of substantial equivalence includes:

Human sensitization, dermal irritation, acute oral toxicity, subacute vaginal irritations, agar diffusion and TSST-1 toxin testing.

2. Based on the review of the data referenced in this "510(k) Summary," the Playtex Tampons are substantially equivalent to the predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1998

Mr. Mark Rosengarten
Director, Regulatory & Biomedical Affairs
Research & Development
215 College Road
P.O. Box 728
Paramus, NJ 07652

Re: K982383
Playtex Tampons #18898, Gentle Glide®, Silk Glide® Slimfits™, Soft Comfort™, and Portables®
Dated: July 7, 1998
Received: July 8, 1998
Regulatory Class: II
21 CFR 884.5460/Procode: 85 HIL
21 CFR 884.5470/Procode: 85 HEB

Dear Mr. Rosengarten:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS OF USE PAGE

510(k) Number (if known): K982383

Device Name: Playtex Gentle Glide®, Silk Glide®, Slimfits™ Soft Comfort™ and Portable® Tampons

Indications For Use:

Scented, Scented Deodorant and Unscented menstrual tampons for absorption of menstrual fluid: Part 21 C. F. R., Section 884.5460 and Section 884.5470 respectively.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982383

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)