

K 971979

1191

9. 510(k) SUMMARY

A. SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 26 1997

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 Affairs  
DATE OF SUMMARY - May 28, 1997
2. DEVICE NAME - Playtex Tampons  
CLASSIFICATION NAME - Unscented Menstrual Tampons
3. The new Playtex tampons are substantially equivalent to previously cleared Playtex Gentle Glide®, Silk Glide®, Slimfits™, Soft Comfort™ and Portables® 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. 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.

3. 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 26 1997

Mr. Mark E. Rosengarten  
Director  
Playtex Products, Inc.  
215 College Road, P.O. Box 728  
Paramus, New Jersey 07652

Re: K971979  
Playtex Gentle Glide®, Silk Glide®, Slimfits™  
Soft Comfort™ and Portable® Tampons  
Dated: August 14, 1997  
Received: August 18, 1997  
Regulatory class: II  
21 CFR §884.5460/Product code: 85 HIB  
21 CFR §884.5470/Product code: 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 requirement, 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/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**

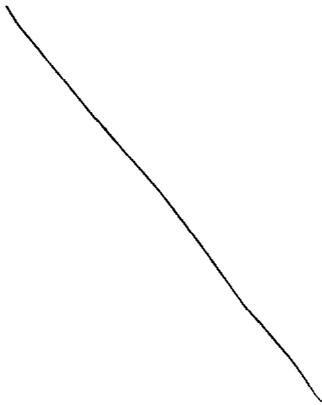
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510(k) Number (if known): K971979

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. Rathjens  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

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Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)