

FEB 7 2000

K993794

9. 510(k) SUMMARY

A. SUMMARY OF SAFETY AND EFFECTIVENESS

1. COMPANY NAME - Playtex Products Inc.
ADDRESS - 75 Commerce Drive
Allendale, New Jersey 07401
TELEPHONE - 201-785-8000
CONTACT PERSON - M. Rosengarten
Director of Regulatory & Biomedical
Affairs
DATE OF SUMMARY - November 5, 1999
 2. DEVICE NAME - Playtex Tampons
CLASSIFICATION NAME - Unscented Menstrual Tampons
 3. The new Playtex tampons are substantially equivalent to previously cleared Playtex Gentle Glide® and Silk Glide®, Regular, Super and Super Plus tampons, and Slimfits® Regular and Super tampons.
 4. The device description is: Unscented menstrual tampons for the absorption of menstrual fluid.
 5. Playtex tampons are intended to be used as 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, Dioxin analysis 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.

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CONFIDENTIAL

10. REQUEST FOR TREATMENT AS CONFIDENTIAL COMMERCIAL INFORMATION UNDER 21 C.F.R. 807.95 (b) AND REQUEST FOR CONTINUING CONFIDENTIALITY UNDER 807.95(C)(3).

I, Dr. Irwin Butensky, Sr. Vice President, R&D, Playtex Products, Inc., ("Playtex") certify as follows:

- (i) Playtex deems its intent to market Playtex Tampons #30999 to be confidential commercial information.
- (ii) To the best of Playtex's knowledge, neither I nor anyone else has disclosed Playtex's intent to market the subject device through advertising or any other manner, to scientists, market analysts, exporters, or other individuals or companies, except to employees of or paid consultants to Playtex or to individuals in an advertising firm pursuant to commercial arrangements with appropriate safeguards for secrecy.
- (iii) Playtex shall notify the FDA immediately if its intent to market the device is disclosed to anyone, except to its employees, or to its paid consultants or individuals such as in an advertising or law firm, pursuant to commercial arrangements with appropriate safeguards for secrecy.
- (iv) Playtex has taken precautions to protect the confidentiality of its intent to market Playtex tampons #30999.
- (v) I understand that submission of false information to the U.S. Government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(g).

Respectfully submitted,


Irwin Butensky



FEB 7 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mark Rosengarten
Director
Regulatory & Biomedical Affairs
Research & Development
Playtex Products, Inc.
Technical Center
75 Commerce Drive
Allendale, NJ 07401-1600

Re: K993794
Playtex Odor Absorbing Gentle Glide®
Slimfits® and Silk Glide® Tampons
Dated: November 5, 1999
Received: November 9, 1999
Regulatory Class: II
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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K 993794

Device Name: Playtex Odor Absorbing Gentle Glide®, Slimfits® and Silk Glide® Tampons

Indications For Use:

Unscented menstrual tampons for absorption of menstrual fluid.

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


Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K 993794