

9. 510(k) SUMMARY

MAY 21 1997

A. SUMMARY OF SAFETY AND EFFECTIVENESS

K971174

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 19, 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 Tampons, Regular, Super and Super Plus.
4. The device description is: Unscented menstrual tampons for the absorption of menstrual fluid.
5. Playtex Gentle Glide 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 and have the same mode of action.

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

Dioxin analysis, 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

MAY 21 1997

Irwin Butensky, Ph.D.
Senior Vice President of R&D
Playtex Products, Inc.
215 College Road, P.O. Box 728
Paramus, New Jersey 07652

Re: K971174
Playtex Tampons #08597
Dated: March 26, 1997
Received: March 31, 1997
Regulatory class: II
21 CFR §884.5470/Product code: 85 HEB

Dear Dr. Butensky:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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

Page 1 of 1

510(k) Number (if known): K971174

Device Name: Playtex Gentle Glide Tampon

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)

Robert D. Rathbone

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K971174

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use +

(Optional Format 1-2-96)