K081535

JUN 27 2008

Section 5: 510(k) Summary

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Lenore Faulhaber, Ph.D., M.B.A. Regulatory Affairs Manager (513) 634-2466 (voice) (513) 634-7364 (FAX)
Date Summary Prepared:	June 2, 2008
Trade Name:	TAMPAX® Pearl Tampons, unscented and scented
Common Name:	Unscented Tampon and Scented Tampon
Classification Name:	Unscented menstrual tampon (21 CFR 884.5470) Scented or scented deodorized menstrual tampon (21 CFR 884.5460)
Predicate Devices:	TAMPAX Pearl Tampons® unscented and scented K011996; K040312; K051290
Device Description:	Scented or scented deodorized, unscented menstrual tampons for absorption of menstrual fluid.
Intended Use:	TAMPAX Pearl Tampons® unscented and scented are intended to be inserted into the vagina to absorb menstrual fluid

Technological Characteristics: The device is similar to the predicate devices in terms of basic component materials, overall design and labeling. The device is designed to acquire and hold menstrual fluids similar to the fluid handling capabilities of the predicate devices.

Safety Assessment: A battery of safety evaluations were conducted, including *in vitro* microbiological testing, biocompatibility evaluation and extraction testing, to evaluate the safety profile of the 510(k) device. The results of these safety tests support the conclusion that the 510(k) device is equally as safe as the predicate devices.

Conclusions: The results of evaluations for this device support the conclusions that it is safe for its intended use and substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Lenore Faulhaber, Ph.D., M.B.A.
Regulatory Affairs Manager
The Proctor & Gamble Company
6110 Center Hill Avenue
CINCINNATI OH 45224

Re: K081555
Trade Name: TAMPAX® Pearl Plastic Tampons (Scented and Unscented)
Regulation Number: 884.5460, 884.5470
Regulation Name: Menstrual Tampons (scented, unscented)
Regulatory Class: II
Product Code: HIL
Dated: June 2, 2008
Received: June 3, 2008

Dear Dr. Faulhaber:

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 such 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 Section 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known) K081555

Device Name TAMPAX® Pearl Plastic™ Tampons

Indications for Use The TAMPAX® Pearl Plastic™ unscented and scented Tampons are intended to be inserted into the vagina to absorb 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_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081555