JUN 2 0 2013

P&G

The Procter & Gamble Company
The Winton Hill Business Center
Product Safety & Regulatory Affairs
6110 Center Hill Avenue
Cincinnati, OH 45224
www. pg.com

Section 5: 510(k) Summary

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Kathleen Blieszner, Ph.D. Regulatory Affairs Manager (513) 634-3168 (voice) (513) 277-2931 (FAX)
Date Summary Prepared:	May 28, 2013
Trade Name:	TAMPAX® L Plastic Applicator Tampons, unscented
Common Name:	Unscented Tampon
Classification Name:	Unscented menstrual tampon (21 CFR 884.5470, Product Code HEB)
Predicate Device:	TAMPAX Pearl® Tampons, unscented K081555
Device Description:	Unscented menstrual tampons for absorption of menstrual fluid. The tampon is a conventional design consisting of an absorbent pledget, an overwrap, a withdrawal cord and an applicator. The materials of construction are cotton, rayon, polypropylene and polyester. The device functions by absorbing menstrual fluid after being inserted into the vagina.
Intended Use:	TAMPAX® L Plastic Applicator Tampons, unscented, are intended to be inserted into the vagina to absorb menstrual fluid.

P&G

Technological Characteristics: The device is similar to the predicate device in terms of basic component materials, overall design and labeling. Both the predicate and the 510(k) device have a chevron-shaped pad of absorbent fibers overwrapped widthwise; a cotton withdrawal cord sewn lengthwise through the middle of the overwrapped pad with blue dyed polypropylene fibers knitted into the cord at the base of the pledget. The device is designed to acquire and hold menstrual fluids similar to the fluid handling capabilities of the predicate device. A new color has been added to the applicator and applicator dimensions for some absorbencies have been changed. The subject device and the predicate device have the same performance characteristics and equivalent safety and efficacy profiles.

Safety Assessment: Tampon material safety and design have been established in 510(k) submission K081555. Biocompatibility testing of each material in the tampon has been completed in previously cleared similar 510(k) devices.

Nonclinical Tests: Extractions of the 510(k) device plastic applicators were performed under exaggerated conditions to confirm negligible or no tampon pledget exposure to the applicator components. Results of the Syngyna, expulsion force, and tampon withdrawal cord anchor strength testing show no change in parameters from the predicate device and confirm that the changes do not impact safety of the device.

Conclusions: The tampon pledget design was not changed from the predicate device. The results of evaluation of the nonclinical testing for this device support the conclusions that the subject device is safe for its intended use and is substantially equivalent to the cited predicate device. Syngyna, expulsion force and tampon withdrawal cord anchor strength testing results are within acceptable limits and similar to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

The Procter & Gamble Company
% Kathleen Blieszner, Ph.D.
Regulatory Affairs Manager
6110 Center Hill Avenue
CINCINNATI OH 45224

Re: K131543
Trade/Device Name: TAMPAX® L Plastic Applicator Tampons, unscented
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: May 28, 2013
Received: May 29, 2013

Dear Dr. Blieszner:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)	K131543
Device Name	TAMPAX® L Plastic Applicator Tampons, unscented
Indications for Use	The TAMPAX® L Plastic Applicator Tampons, unscented, are intended to be inserted into the vagina to absorb menstrual fluid.

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801. 109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S