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4. 510(k) Summary K040999

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Mark M. Anderson, Regulatory Affairs Manager (513) 634-5196 (voice) (513) 634-7364 (FAX)
Date Summary Prepared:	April 15, 2004
Trade Name:	TAMPAX® Tampons
Common Name:	Unscented Menstrual Tampon
Classification Name:	Unscented Menstrual Tampon (per 21 CFR 884.5470)
Predicate Device:	TAMPAX® Tampons, Procter & Gamble, K002096

Device Description: The device is a conventional unscented menstrual tampon consisting of an absorbent pledget, a withdrawal cord, and an applicator.

- The absorbent pledget consists of a pad of cotton and/or rayon fibers overwrapped with a non-woven fabric. A cotton withdrawal cord is sewn to the pad, and the pad is compressed into a traditional bullet-shaped pledget.
- The formed pledget is inserted into a flushable paper applicator consisting of an inner pusher tube and an outer insertion tube with an open distal end.
- Each tampon is wrapped in an individual wrapper and packaged in sealed multi-unit containers for retail sale.

Intended Uses: The device is intended to be inserted into the vagina to absorb menstrual fluid.

Technological Characteristics: The device is similar to the predicate device in terms of component materials, overall design and labeling. It differs from the predicate device in the composition of the non-woven pledget overwrap material.

Safety Assessment: This safety assessment of the 510(k) device was based on a battery of safety tests, including *in vitro* testing and biocompatibility testing.

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The results of these safety tests support the conclusion that this 510(k) device is equally as safe as the predicate device.

Effectiveness. The TAMPAX® Tampons 510(k) device complies with the syngyna absorbency requirements of 21 CFR 801.430. Therefore, additional testing of these tampons is not necessary to establish their equivalence to the predicate tampon in terms of effectiveness.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2004

Mark M. Anderson, Ph.D.
Regulatory Affairs Manager
The Procter & Gamble Company
Feminine Care Global Business Unit
6110 Center Hill Avenue
CINCINNATI OH 45224

Re: K040999
Trade/Device Name: TAMPAX® Tampons – (Junior, Regular, Super and Super Plus Absorbencies)
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 78 HEB
Dated: April 15, 2004
Received: April 19, 2004

Dear Dr. Anderson:

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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

3. Statement of Indications for Use

510(k) Number (if known) K040999

Device Name: TAMPAX® Tampons

Indications for Use:

TAMPAX® Tampons are unscented menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Supbart D) (21 CFR Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040999