SEP 1 9 2001

K011996
Page 1 of 2

ORIGINAL 510(k) APPLICATION (TRADITIONAL)

1. General Information

A. *Application Date:* June 26, 2001

B. *Applicant Name:* The Procter & Gamble Company
Feminine Care Global Business Unit

Address: 6110 Center Hill Avenue
Cincinnati, OH 45224

Establishment Registration Number: 1523399

Contact Person: Mark M. Anderson, Ph.D.
Regulatory Affairs Manager

Phone: (513) 634-5196

FAX: (513) 634-7364

E-mail: anderson.mm.1@pg.com

C. *Trade Name of the Device:*
TAMPAX® Pearl Scented Tampons - Plastic Applicator (Junior, Regular, Super, and Super Plus Absorbencies)

TAMPAX® Pearl Tampons (unscented) - Plastic Applicator (Junior, Regular, Super, and Super Plus Absorbencies)

D. *Common Name of the Device:* Scented Menstrual Tampon,
Unscented Menstrual Tampon

E. *Manufacturing Facility:*

Tambrands Manufacturing Inc.
2879 Hotel Road
Auburn, ME 04210

Establishment Registration Number: 1219109

Phone: (207) 753-4000

FAX: (207) 786-5269

Contact: Jeff Gendron, Site Quality Manager

E-mail: gendron.ja@pg.com

- Each tampon is wrapped in an individual plastic film 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 devices in terms of component materials, overall design (see *Device Description*, above), and labeling. This device differs from the predicate devices in the shape of the uncompressed absorbent pad, the composition of the pad overwrap material, the inclusion of absorbent fiber in a portion of the withdrawal cord, the composition of the fragrance used in the scented tampon, and the color of the plastic applicator.

Safety Assessment: This 510(k) device was subjected to an extensive battery of safety tests, including *in vitro* microbiological testing, biocompatibility testing, and safety-in-use clinical testing of the finished product. The results of these safety tests support the conclusion that this 510(k) device is equally as safe as the predicate devices.

Effectiveness: TAMPAX® Pearl Scented Satin Tampons and TAMPAX® Pearl Unscented Tampons comply 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 tampons 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 devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

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

Re: K011996
Trade/Device Name: Scented and Unscented Menstrual Tampons
Regulation Number: 21 CFR 884.5460
Regulation Name: Scented or unscented deodorized Menstrual tampon
Product Code: 85 HIL
Regulatory Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Product Code: 85 HEB
Regulatory Class: II
Dated: June 26, 2001
Received: June 27, 2001

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 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 this 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" (21 CFR Part 807.97). 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): K011996

Device Name: TAMPAX® Pearl Scented Tampons & TAMPAX® Pearl Tampons (unscented)

Indications for Use:

TAMPAX® Pearl Scented Tampons & TAMPAX® Pearl Unscented Tampons are menstrual tampons that are inserted into the vagina and used 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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011996