K012629
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OCT - 5 2001

4. 510(k) Summary

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:	August 9, 2001
Trade Name:	P&G Miniform #3 P&G Unscented Menstrual Pad
Common Name:	Interlabial Pad, Miniform
Classification Name:	Unscented Menstrual Pad (per 21 CFR 884.5435)
Predicate Device:	P&G Miniform #2, K003843

Device Description: The interlabial pad device has 3 primary components:

1. The permeable topsheet allows fluid to pass through into the core.
2. The absorbent core acquires and stores the fluid.
3. The impermeable backsheet prevents fluid transfer beyond the core.

The absorbent core is held in place between the topsheet and backsheet, which are bonded at the perimeter to form an ellipse-shaped trilaminate structure. An attached tab glued onto the backsheet extends from the back of the device as an aid for application and removal.

The device will be individually wrapped and packaged in sealed multi-unit containers for retail sale.

Intended Uses: For absorption of menstrual or other vaginal discharge, and for absorption of slight urine loss associated with light incontinence.

Technological Characteristics: The device is designed to absorb fluids emanating from the female urogenital region. It is folded in half longitudinally for application, and held in place by the labia (without adhesives) at the exterior of the vagina, covering the introital opening and urethral meatus. The device is removed by urination or may be removed manually.

The device's ability to absorb fluid is based on an absorbent fiber core, and is similar to the absorbent technology of the predicate device. The

placement, retention and removal characteristics of the device are identical to those of the predicate device.

Clinical Performance: The safety profile of the new device is substantially equivalent to the safety profile of the predicate device, based on the results of biocompatibility testing of component materials of the new device and on the results of a clinical safety test of the new device.

The predicate device has been available in a limited test market. There have been no skin or health-related consumer comments regarding this product.

Conclusions: The similarity of the safety profile of the new device to the predicate device and the lack of negative comments from the predicate device market experience to date indicates that the new device is safe for its intended uses, 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

OCT - 5 2001

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

Re: K012629
Trade/Device Name: Always® Duets-Unscented Interlabial Pad (Miniform #3) and Menstrual Pad
Regulation Number: 21 CFR 884.5435
Regulation Name: Unscented menstrual pad
Regulatory Class: I
Product Code: 85 HHD
Dated: August 9, 2001
Received: August 13, 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): K012629

Device Name: P&G Miniform # 3 Unscented Interlabial Menstrual Pad and P&G Unscented Menstrual Pad

Indications for Use:

The P&G Miniform #3 Unscented Interlabial Menstrual Pad can be worn any time of the day or night in the following ways:

- Alone for light and medium (menstrual) flow
- In combination with tampons or pads for extra protection during heavy (menstrual) flow
- Alone for vaginal discharge or slight urine loss associated with laughs, coughs, and sneezes.

The P&G Unscented Menstrual Pad can be worn any time of the day or night in the following ways:

- For menstrual flow or other vaginal discharge

(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)

Carolyn Y Neuland

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012629

(Optional Format 1-2-96)