FEB 14 2000 K993870

4. 510(k) Summary

Submitted by:	The Procter & Gamble Company 6100 Center Hill Avenue Cincinnati, OH 45240
Contact Person:	Mark M. Anderson, Regulatory Affairs Manager (513) 634-5196 (voice) (513) 634-7364 (FAX)
Date Summary Prepared:	November 11, 1999
Trade Name:	Unscented Interlabial Menstrual Pad
Common Name:	Interlabial Pad
Classification Name:	Unscented Menstrual Pad (per 21 CFR 884.5435)
Predicate Devices:	Fresh 'n Fit Padette®, Xtramedics, Inc., K881384 Always® Unscented Pantiliners, Procter & Gamble, K844601

Device Description: The 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 ovoid trilaminate structure. A tab formed from 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 both predicate devices. The trilaminate structure of the device is similar to the laminate structure of the Always® Pantiliner predicate device. The placement, retention and removal

characteristics of the device are similar to those of the Fresh 'n Fit Padette® predicate device.

Non-Clinical Performance: Microbiological (*in vitro*) testing of the backsheet material and of the whole product confirmed the microbiological stability of the product. Analytical testing of the backsheet material confirmed the stability of the backsheet.

Clinical Performance: Under the conditions of the study the results of Cumulative Irritation and Sensitization tests of components of the interlabial pad showed that the materials used in the product do not have any adverse dermatological effects. A clinical study using the whole product indicated that this interlabial pad had no negative impact on vulvar skin or on vulvar and vaginal microflora. Consumer preference testing showed a high level of satisfaction among women who used the product. A small percentage of users reported minor complaints related to discomfort (itching, chafing, etc.), none of which required medical intervention.

Conclusions: The results of the preclinical and clinical testing of this device demonstrate that it is safe for its intended uses, 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

FEB 14 2000

Mark M. Anderson, Ph.D.
Regulatory Affairs Manager
Procter & Gamble
Winton Hill Technical Center
6100 Center Hill Avenue
Cincinnati, OH 45224-1788

Re: K993870
Unscented Interlabial Menstrual Pad
Regulatory Class: I
21 CFR §884.5435/Procode: 85 HHD
Dated: November 11, 1999
Received: November 15, 1999

Dear Dr. Anderson:

This letter corrects our substantially equivalent letter of January 18, 2000, regarding the change in the trade name.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive, Abdominal,
Ear, Nose and Throat, 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): K993870

Device Name: Unscented Interlabial Menstrual Pad

Indications for Use:

The 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.

(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, ENT, and Radiological Devices
510(k) Number K993870

(Optional Format 1-2-96)