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4. 510(k) Summary K003843

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Kathleen C. Blieszner, Regulatory Affairs Manager (513) 634-3265 (voice) (513) 634-7364 (FAX)
Date Summary Prepared:	December 8, 2000
Trade Name:	P&G Miniform #2 P&G Unscented Menstrual Pad
Common Name:	Interlabial Pad, Menstrual Pad
Classification Name:	Unscented Menstrual Pad (per 21 CFR 884.5435)
Predicate Device:	Envive Miniform, Procter & Gamble, K993870

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 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 Envive Miniform predicate device K993870.

Clinical Performance: The safety profile of the new device is substantially equivalent to the safety profile of the Envive miniform predicate device; therefore a safety-in-use clinical was not conducted.

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 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

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Kathleen Blieszner, Ph.D.
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The Procter & Gamble Company
Feminine Care Global Business Unit
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CINCINNATI OH 45224

Re: K003843
P&G Miniform #2 Unscented Interlabial Menstrual Pad and P&G Unscented Menstrual Pad
Dated: December 8, 2000
Received: December 12, 2000
Regulatory Class: II
21 CFR §884.5435/Procode: 85 HHD

Dear Dr. Blieszner:

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

3. Statement of Indications for Use

510(k) Number (if known): K003843

Device Name: P&G Miniform # 2 Unscented Interlabial Menstrual Pad and P&G Unscented Menstrual Pad

Indications for Use:

The P&G Miniform #2 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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003843