K071827

Section 5: 510(k) Summary

9-20-07

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Lenore Faulhaber, Ph.D., M.B.A. Regulatory Affairs Manager (513) 634-2466 (voice) (513) 634-7364 (FAX)
Date Summary Prepared:	July 2, 2007
Trade Name:	Always® unscented menstrual pad
Common Name:	Unscented Menstrual Pad
Classification Name:	Unscented Menstrual Pad (21 CFR 884.5435)
Predicate Devices:	Always® ultra thin unscented menstrual pad Always® Curves unscented menstrual pads (K922575/A)

Device Description: The menstrual pad device has 4 primary components, 1) The permeable topsheet allows fluid to pass through into the core; 2) the absorbent core acquires and stores fluid; 3) the impermeable backsheet prevents fluid transfer beyond the core; 4) the attachment adhesive holds the pad in place. The absorbent core is held in place between the topsheet and the backsheet.

Intended Uses: Always® are unscented menstrual pads for absorption of menstrual fluid and other vaginal discharge, and for absorption of urine loss associated with light incontinence.

Technological Characteristics: The device is designed to acquire and hold menstrual fluids or light urine loss similar to the fluid handing capabilities of the predicate devices.

Safety Assessment: A battery of safety tests was conducted, including *in vitro* microbiological testing, biocompatibility testing and extraction testing, to evaluate the safety profile of the 510(k) device. The results of these safety tests support the conclusion that the 510(k) device is equally as safe as the predicate devices.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 20 2007

Ms. Lenore Faulhaber, Ph.D.,M.B.A.
Regulatory Affairs Manager
The Procter & Gamble Company
Product Safety & Regulatory Affairs
6110 Center Hill Avenue
CINCINNATI OH 45224

Re: K071827
Trade Name: Always® Unscented Menstrual Pads
Regulation Number: 21 CFR §886.5435
Regulation Name: unscented menstrual pad
Regulatory Class: I
Product Code: HHD
Dated: July 2, 2007
Received: July 3, 2007

Dear Dr. Faulhaber:

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 (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 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Section 4: Indications for Use Statement

510(k) Number (if known): K071827

Device Name: Always® unscented menstrual pad

Indications for Use:

Always® are unscented menstrual pads for absorption of menstrual and other vaginal discharge, and for absorption of urine loss associated with light incontinence due to stress-related activities such as laughs, coughs, sneezes and exercise.

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 K071827