K091084

APR 29 2009

ANNEX 12

COHITECH	TECHNICAL EVALUATION DOCUMENTATION	# Document: COTTON MENSTRUAL TAMPONS

SECTION E – UNSCENTED COTTON MENSTRUAL TAMPON: 510(k) SUMMARY

DATE OF SUBMISSION: 2008-09-01

SUBMITTER NAME: COTTON HIGH TECH SL
SUBMITTER ADDRESS: Ctra Navas a Prats de Lluçanès KM1,5
08679 Gaià
BARCELONA
SPAIN

CONTACT: Elena Gomez
Safety Officer
TELEPHONE: + 34 93 839 16 28
FAX: + 34 93 839 19 44
e-mail: egomez@cohitech.net

DEVICE TRADE NAME: **COTTON MENSTRUAL TAMPONS**
MAXIM MENSTRUAL TAMPONS
ORGANYC MENSTRUAL TAMPONS

COMMON NAME: TAMPON, MENSTRUAL, UNSCENTED
CLASSIFICATION NAME: TAMPON, MENSTRUAL, UNSCENTED
(21 CFR 884.5470)
DEVICE CLASS: II

PREDICATE DEVICE(S): TAMPAX® Tampons (The Procter & Gamble Company – K061486)
NATRACARE TAMPON (Bodywise UK – K954942)

DEVICE DESCRIPTION: The device is a conventional unscented menstrual tampon consisting of an absorbent pledget, a withdrawal cord, and an applicator.
These tampons will be provided as three absorbencies: regular, super and super plus.
Each tampon is wrapped in an individual wrapper and packaged in sealed multi-unit containers for retail sale.

INTENDED USE: The device is intended to be inserted into the vagina to absorb menstrual fluid.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:
In the establishment of substantial equivalence, COTTON MENSTRUAL TAMPONS is compared with another device TAMPAX® Tampons (The Procter & Gamble Company) and with NATRACARE TAMPON (Bodywise UK). The following table summarizes the similarities of the principal

technological characteristics and features of both predicate and new devices.

#	Characteristic / Feature	COTTON MENSTRUAL TAMPONS	PREDICATES	
			TAMPAX® Tampons (The Procter & Gamble Company – K061486)	NATRACARE TAMPON (Bodywise UK – K954942)
1.	Intended use	The device is intended to be inserted into the vagina to absorb menstrual fluid	The device is intended to be inserted into the vagina to absorb menstrual fluid	The device is intended to be inserted into the vagina to absorb menstrual fluid
2	Indication for use	Absorb menstrual or other vaginal discharge	Absorb menstrual or other vaginal discharge	Absorb menstrual or other vaginal discharge
3	Design	Cylindrical shape. Applicator with silky and rounded tip	Cylindrical shape. Applicator with silky and rounded tip	Cylindrical shape. Applicator with silky and rounded tip
4.	Technological features:			
		REGULAR		
	Dimensions Length diameter	Tampon: 47.5 mm ± 5% Applicator:120 mm ± 5% Tampon: 12 mm Applicator: 14 mm	Tampon: 47 mm Applicator: 120 mm Tampon: 12.5 mm Applicator: 14 mm	Tampon: 46 mm Applicator: 125 mm Tampon: 13 mm Applicator: 14 mm
	Absorbency (grams) for each level	6-9 g	6-9 g	6-9 g
		SUPER		
	Dimensions Length diameter	Tampon: 47.5 mm ± 5% Applicator:120 mm ± 5% Tampon: 14 mm Applicator: 16 mm	Tampon: 47 mm Applicator: 120 mm Tampon: 14 mm Applicator: 16 mm	Tampon: 47 mm Applicator: 125 mm Tampon: 14 mm Applicator: 16 mm
	Absorbency (grams) for each level	9-12 g	9-12 g	9-12 g
		SUPER PLUS		
	Dimensions Length diameter	Tampon: 47.5 mm ± 5% Applicator:120 mm ± 5% Tampon: 14 mm Applicator: 16 mm	Tampon: 47 mm Applicator: 120 mm Tampon: 14 mm Applicator: 16 mm	NA
	Absorbency (grams) for each level	12-15 g	12-15 g	NA
5.	Materials	**REGULAR, SUPER AND SUPER PLUS** 100% Organic Cotton Absorbent Core 100% Organic Cotton Nonwoven Fiber Cardboard Applicator Withdrawal cord, cotton yarn	Viscose Absorbent Core Polypropylene /Polystyrene Nonwoven Cardboard Applicator Withdrawal cord, cotton yarn	100% Organic Cotton Absorbent Core 100% Organic Cotton Nonwoven Fiber Cardboard Applicator Withdrawal cord, cotton yarn

SECTION E – UNSCENTED COTTON MENSTRUAL TAMPON: 510(k) SUMMARY

#	Characteristic / Feature	COTTON MENSTRUAL TAMPONS	PREDICATES	
			TAMPAX® Tampons (The Procter & Gamble Company – K061486)	NATRACARE TAMPON (Bodywise UK – K954942)
		Sewing yarn, 66% Polyester, 34% Cotton Wrapping foil, cellulose paper	Sewing yarn, 66% Polyester, 34% Cotton Wrapping foil, cellulose paper	Sewing yarn, 66% Polyester, 34% Cotton Wrapping foil, cellulose paper
6.	Additives and finishing Agents	No contain	No contain	No contain
7.	Biological Specifications	Non sterile, single-use only	Non sterile, single-use only	Non sterile, single-use only
8.	Other features	-	-	-

Table 5.1 – Summary comparison of proposed device with predicate devices

From the above table, it can be established that the new device and the predicates devices Tampax Tampons and Natracare Tampons have identical intended uses and indications and similar technological features (dimensions and absorbency).
Also, the materials used in the construction of the proposed device and those used in the predicate device Natracare are identical.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

All materials used in the construction of COTTON MENSTRUAL TAMPONS have been subject to chemical and biological testing in accordance with the applicable requirements taking account of its intended use. The results of these safety tests support the conclusion that this device is safe for use.

Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use and absorbency requirements. Therefore the proposed devices are equivalent to the predicates in terms of effectiveness.

CONCLUSIONS:

We believe the intended use, the indications for use, the safety , effectiveness and functionality of COTTON MENSTRUAL TAMPONS and the TAMPAX and NATRACARE predicate devices as unscented menstrual tampon are essentially the same. Also, the materials used in the construction of the proposed device and those used in the predicate device NATRACARE are identical. Hence, substantial equivalence of COTTON MENSTRUAL TAMPONS with the legally marketed devices may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cotton High Tech SL
c/o Mr. Casey Conry
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

APR 29 2009

Re: K091084
Trade/Device Name: COTTON MENSTRUAL TAMPONS
MAXIM MENSTRUAL TAMPONS
ORGANYC MENSTRUAL TAMPONS
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampons
Regulatory Class: II
Produce code: HEB
Dated: April 13, 2009
Received: April 15, 2009

Dear Mr. Conry:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

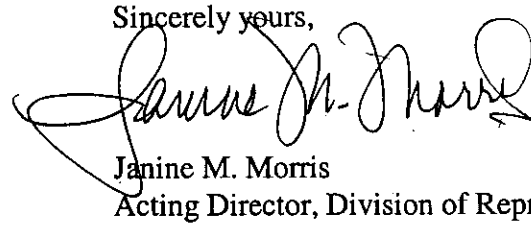
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.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). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K091084

Device Name: COTTON MENSTRUAL TAMPONS:
MAXIM MENSTRUAL TAMPONS
ORGANYC MENSTRUAL TAMPONS

Indications for Use:

Cotton menstrual tampons are unscented menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Prescription Use ____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _X_ (21 CFR 801 Subpart C)

(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 K091084