K090098

510(k) SUMMARY

JAN 30 2009

November 24, 2008

Company	Maxim Hygiene Products 39 Maple Street Roslyn Heights, NY 11577-1941
Contact:	Kenneth Alvandi CEO Phone: 516-6212-3323 Fax: 516-621-3312
Device Classification Name:	Tampon, Menstrual, Unscented
Proprietary Name:	Maxim Hygiene Organically Grown Cotton Tampon
Regulation Number:	21 CFR 884.5470
Product Code:	HEB
Predicate Device(s):	K983478 Organic Essentials Organic Cotton Tampon K914430 Natracare Tampon

11.0 Intended Use:

Maxim Hygiene Organically Grown Cotton Tampon is a tampon used to absorb menstrual fluid.

The intended use of the organic cotton tampon is the same as all other products that are legally marketed.

11.1 Product Description

A tampon is used for internally absorbing menstrual flow during a period. A range of absorbencies are available designed to cope with various menstrual flows which differ not only from woman to woman, but also during a woman's menstrual life and during each period. Typically 80% of fluid is lost in the first two days and some 60 mls. (an egg cup full) to 90 mls. in a full period. This underlines the need for users to change products throughout their period and for manufacturers to offer a wide range of products for their users.

Biocompatibility requirements were addressed in K983478 and K914430 based on the fact that Maxim Hygiene's tampons are identical to the cleared devices found in K983478 and K914430.

12.2 Summary of Safety and Effectiveness

The Maxim Hygiene Organically Grown Cotton Tampon based on the following comparisons demonstrate substantial equivalent. The device subject to this review is manufactured by the same manufacturer and is identical to the predicate devices does not raise any new issues as to safety and effectiveness.

The following tests were also performed to support substantial equivalence:

- Determination of Absorbency Rate of Tampons = Syngina Test
- Expulsion Force Applicator Tampons
- Fiber Loss ATS Testing Method
- Stability Check on Digital Tampons

Applicator Tampon Super with Crown End

Parameters	**Maxim Hygiene Products**	**Organic Essentials**	**Bodywise**
510(k) Number		K983478	K914430
Intended Use Statement	Maxim Hygiene Organically Grown Cotton Tampon is a tampon that is inserted into the vagina and used to absorb menstrual fluid. The intended use of the organic cotton tampon is the same as all other products that are legally marketed.	Organic Essentials Organically Grown Cotton Tampon is a tampon that is inserted into the vagina and used to absorb menstrual fluid. The intended use of the organic cotton tampon is the same as all other products that are legally marketed.	Natracare Tampon is a tampon that is inserted into the vagina and used to absorb menstrual fluid. The intended use of the organic cotton tampon is the same as all other products that are legally marketed.
Applicator Tampon Super with Crown End			
Dimensions			
Total Weight	5,0-5,9g	5,0-5,9g	5,0-5,9g
Weight without applicator	2,7-3,2g	2,7-3,2g	2,7-3,2g
Withdrawal Cord	115-175 mm	115-175 mm	115-175 mm
Length with Applicator	120-125 mm	120-125 mm	120-125 mm

Length without Applicator	45-50 mm	45-50 mm	45-50 mm
Diameter with Applicator	15,9-16,1g	15,9-16,1g	15,9-16,1g
Diameter without Applicator	14,2-15,7g	14,2-15,7g	14,2-15,7g
Syngina Absorption	9,0-12,0g	9,0-12,0g	9,0-12,0g
Wadding	100% organic cotton	100% organic cotton	100% organic cotton
Non Woven	100% organic cotton	100% organic cotton	100% organic cotton
Withdrawal Cord	100% organic cotton	100% organic cotton	100% organic cotton
Applicator	Cardboard	Cardboard	Cardboard

Digital Tampons Regular

Parameters	**Maxim Hygiene Products**	**Organic Essentials**	**Bodywise**
510(k) Number		K983478	K914430
Intended Use Statement	Maxim Hygiene Organically Grown Cotton Tampon is a tampon that is inserted into the vagina and used to absorb menstrual fluid. The intended use of the organic cotton tampon is the same as all other products that are legally marketed.	Organic Essentials Organically Grown Cotton Tampon is a tampon that is inserted into the vagina and used to absorb menstrual fluid. The intended use of the organic cotton tampon is the same as all other products that are legally marketed.	Natracare Tampon is a tampon that is inserted into the vagina and used to absorb menstrual fluid. The intended use of the organic cotton tampon is the same as all other products that are legally marketed.
Digital Tampon Regular			
Dimensions			
Weight with Single Packaging	2,1-2,5g	2,1-2,5g	2,1-2,5g
Weight Tampon	2,0-2,4g	2,0-2,4g	2,0-2,4g
Length with Single Packaging	42-26 mm	42-26 mm	42-26 mm
Diameter with Single Packaging	11,8-12,2 mm	11,8-12,2 mm	11,8-12,2 mm

Withdrawal Cord	130-160 mm	130-160 mm	130-160 mm
Syngina Absorption	6,0-9,0g	6,0-9,0g	6,0-9,0g
Wadding	100% organic cotton	100% organic cotton	100% organic cotton
Withdrawal Cord	100% organic cotton	100% organic cotton	100% organic cotton

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Maxim Hygiene Products, Inc.
c/o Mr. Neil E. Devine, Jr.
Sr. Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

JAN 30 2009

Re: K090098
Trade/Device Name: Maxim Hygiene Organically Grown Cotton Tampon
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: January 12, 2009
Received: January 15, 2009

Dear Mr. Devine:

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 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/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

Indications for Use

510(k) Number (if known): K09 0098

Device Name: Maxim Hygiene Organically Grown Cotton Tampon

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090098