K090819

DEC 2 3 2009

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMVDA 1990 and 21 CFR §807.92.

510(k) number:

1. Submitter's Identification:
Ontex International NV
Spinnerijstraat 12
9240 Zele
Belgium
Submitter Phone: 0032 / 52 454 651
Submitter Fax: 0032 /52 454 610
Submitter Contact: Steven Smet
Title:

2. Name of the Device: Digital and Applicator Menstrual Tampons
Ontex Tampons (Unscented)
Device Class: II
Regulation: 884.5470
Product Code: HEB

3. Predicate Device Information:
Maxim Hygeine Organically Grown Cotton Tampon
510(k) Number: K090098
Maxim Hygeine Products.
39 Maple Street
Roslyn Heights, NY 11577-1941

4. Device Description:

The tampons to be marketed are conventional unscented menstrual tampons consisting of an absorbent pledget, with and without applicator.

5.0 Device Comparison to Predicate Device(s):

The following tests were performed to support substantial equivalence (see Appendix 2 – Testing):

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

Applicator Tampon

Parameters	**Ontex International**	**Maxim Hygiene Products**
510(k) Number		K090098
Dimensions		
Total Weight	5,0-5,9g	5,0-5,9g
Weight without applicator	2,7-3,2g	2,7-3,2g
Withdrawal Cord	115-175 mm	115-175 mm
Length with Applicator	120-125 mm	120-125 mm
Length without Applicator	45-50 mm	45-50 mm
Diameter with Applicator	15,9-16,1 mm	15,9-16,1 mm
Diameter without Applicator	14,2-15,7 mm	14,2-15,7 mm
Syngina Absorption	9,0-12,0g	9,0-12,0g
Wadding	100% organic cotton	100% organic cotton
Non Woven	100% organic cotton	100% organic cotton
Withdrawal Cord	100% organic cotton	100% organic cotton
Applicator	Cardboard	Cardboard

Digital Tampon

Parameters	Ontex International	Maxim Hygeine Products K090098
Digital Tampon		
Dimensions		
Weight with Single Packaging	2,1-2,5g	2,1-2,5g
Weight Tampon	2,0-2,4g	2,0-2,4g
Length with Single Packaging	42-26 mm	42-26 mm
Diameter with Single Packaging	11,8-12,2 mm	11,8-12,2 mm
Withdrawal Cord	130-160 mm	130-160 mm
Syngina Absorption	6,0-9,0g	6,0-9,0g
Wadding	100% organic cotton	100% organic cotton
Withdrawal Cord	100% organic cotton	100% organic cotton

Conclusions:

The subject device has the same intended use and technical characteristics as the predicate device. Similarly, there are no differences in materials used to fabricate the subject device and the predicate device. Therefore no new questions of safety or effectiveness are raised by this submission. Thus, the Ontex Tampon (Unscented) is substantially equivalent to the predicate device, the Maxim Hygeine Products Tampon (K090098).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ontex International NV
% Mr. Neal Kolber
Project Manager
Emergo Group
1705 S. Capital of Texas Highway, Suite 500
AUSTIN TX 78746

DEC 23 2009

Re: K090819
Trade/Device Name: Ontex Tampon (Unscented)
Regulation Number: 21 CFR §884.5470
Regulation Name: Menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: November 30, 2009
Received: December 1, 2009

Dear Mr. Kolber:

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 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

K090819

INDICATIONS FOR USE

510(k) Number (if known): K090819

Device Name: Ontex Tampon (Unscented)

Indications for Use:

Ontex 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.

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

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

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090819