



Food and Drug Administration
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April 20, 2015

Tosama D.O.O.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
45 Rockerfeller Plaza, Suite 2000
New York, NY 10111

Re: K150897
Trade/Device Name: Tosama 100% Cotton Menstrual Tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: April 14, 2015
Received: April 15, 2015

Dear Dave Yungvirt,

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,


Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name

Tosama 100% Cotton Menstrual Tampon

Indications for Use (Describe)

The Tosama 100% Cotton Tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary

DATE OF PREPARATION: April 20th, 2015

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DEVICE TRADE NAME: Tosama 100% Cotton Menstrual Tampon

COMMON NAME: Unscented Menstrual Tampon

CLASSIFICATION NAME: Tampon, Menstrual, Unscented

REGULATION NUMBER: 21 CFR §884.5470

PRODUCT CODE: HEB

DEVICE CLASS: II

PREDICATE DEVICES: Naturalena 100% Cotton Tampon (K130609)
Cottons 100% Natural Cotton Tampon (K080733)

DEVICE DESCRIPTION: The device will be offered as a traditional unscented menstrual 100% cotton tampon consisting of an absorbent pledget, a withdrawal cord, and an applicator. The pledget is of the traditional cylindrical, bullet-like shape and the applicator has a standard rounded tip to ease insertion. Each tampon is individually wrapped and packaged in multi-unit containers for retail sale. It will be offered in three absorbencies: Regular, Super, and Super Plus.

INDICATIONS FOR USE: The Tosama 100% Cotton Tampon is intended for insertion into the vagina for absorption of menstrual or other vaginal discharge.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE: The Tosama 100% Cotton Tampon demonstrates substantial equivalence to both the Naturalena 100% Cotton Tampon (K130609) and the Cottons 100% Natural Cotton Tampon (K080733). Table 5-1 summarizes the key technological characteristics and features of both the predicates and the new device.

Table 5-1: Comparison of Proposed Device with Predicate Devices

Feature	Tosama 100% Cotton Tampon	Predicates	
		Naturalena 100% Cotton Tampon	Cottons 100% Natural Cotton Tampon
510(k) Number		K130609	K080733
Indications for Use	The device is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.	The device is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.	The device is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.
Design	Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.	Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.	Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.
Dimensions & Weights	Digital Tampons	Digital Tampons	Digital Tampons
<i>Description:</i>	Regular Digital	Regular Digital	Regular Digital
<i>Length:</i>	43.0mm – 46.0mm	43.0mm – 46.0mm	43.0mm – 46.0mm
<i>Diameter:</i>	11.0mm – 12.0mm	11.0mm – 12.0mm	11.0mm – 12.0mm
<i>Mass:</i>	2.30g – 2.70g	2.30g – 2.70g	2.30g – 2.70g
<i>Withdrawal Cord:</i>	130mm – 160mm	130mm – 160mm	130mm – 160mm
<i>Syngina Absorbency:</i>	6.0g – 9.0g	6.0g – 9.0g	6.0g – 9.0g
<i>Description:</i>	Super Digital	Super Digital	Super Digital
<i>Length:</i>	48.0mm – 51.0mm	48.0mm – 51.0mm	48.0mm – 51.0mm
<i>Diameter:</i>	12.0mm – 13.0mm	12.0mm – 13.0mm	12.0mm – 13.0mm
<i>Mass:</i>	2.70g – 3.10g	2.70g – 3.10g	2.70g – 3.10g
<i>Withdrawal Cord:</i>	130mm – 160mm	130mm – 160mm	130mm – 160mm
<i>Syngina Absorbency:</i>	9.0g – 12.0g	9.0g – 12.0g	9.0g – 12.0g
<i>Description:</i>	Super Plus Digital	Super Plus Digital	Super Plus Digital
<i>Length:</i>	48.0mm – 51.0mm	48.0mm – 51.0mm	48.0mm – 51.0mm
<i>Diameter:</i>	14.0mm – 15.0mm	14.0mm – 15.0mm	14.0mm – 15.0mm
<i>Mass:</i>	3.30g – 3.80g	3.30g – 3.80g	3.30g – 3.80g
<i>Withdrawal Cord:</i>	130mm – 160mm	130mm – 160mm	130mm – 160mm
<i>Syngina Absorbency:</i>	12.0g – 15.0g	12.0g – 15.0g	12.0g – 15.0g
Dimensions & Weights	Applicator Tampons	Applicator Tampons	Applicator Tampons
<i>Description:</i>	Regular Applicator	Regular Applicator	Regular Applicator
<i>Tampon Length:</i>	43.0mm – 46.0mm	43.0mm – 46.0mm	43.0mm – 46.0mm
<i>Applicator Length:</i>	120mm ± 5%	120mm ± 5%	120mm ± 5%
<i>Tampon Diameter:</i>	11.0mm – 12.0mm	11.0mm – 12.0mm	11.0mm – 12.0mm
<i>Applicator Diameter:</i>	13mm	13mm	13mm
<i>Tampon Mass:</i>	2.00g – 2.30g	2.00g – 2.30g	2.00g – 2.30g
<i>Applicator Mass:</i>	3.40g – 3.60g	3.40g – 3.60g	3.40g – 3.60g
<i>Total Mass:</i>	5.40g – 5.90g	5.40g – 5.90g	5.40g – 5.90g
<i>Withdrawal Cord:</i>	130mm – 160mm	130mm – 160mm	130mm – 160mm
<i>Syngina Absorbency:</i>	6.0g – 9.0g	6.0g – 9.0g	6.0g – 9.0g

Feature	Tosama 100% Cotton Tampon	Predicates	
		Naturalena 100% Cotton Tampon	Cottons 100% Natural Cotton Tampon
Description: <i>Tampon Length:</i> <i>Applicator Length:</i> <i>Tampon Diameter:</i> <i>Applicator Diameter:</i> <i>Tampon Mass:</i> <i>Applicator Mass:</i> <i>Total Mass:</i> <i>Withdrawal Cord:</i> <i>Syngina Absorbency:</i>	Super Applicator 43.0mm – 46.0mm 120mm ± 5% 12.0mm – 13.0mm 16mm 2.60g – 3.00g 4.10g – 4.30g 6.70g – 7.30g 130mm – 160mm 9.0g – 12.0g	Super Applicator 43.0mm – 46.0mm 120mm ± 5% 12.0mm – 13.0mm 16mm 2.60g – 3.00g 4.10g – 4.30g 6.70g – 7.30g 130mm – 160mm 9.0g – 12.0g	Super Applicator 43.0mm – 46.0mm 120mm ± 5% 12.0mm – 13.0mm 16mm 2.60g – 3.00g 4.10g – 4.30g 6.70g – 7.30g 130mm – 160mm 9.0g – 12.0g
Description: <i>Tampon Length:</i> <i>Applicator Length:</i> <i>Tampon Diameter:</i> <i>Applicator Diameter:</i> <i>Tampon Mass:</i> <i>Applicator Mass:</i> <i>Total Mass:</i> <i>Withdrawal Cord:</i> <i>Syngina Absorbency:</i>	Super Plus Applicator 43.0mm – 46.0mm 120mm ± 5% 14.0mm – 15.0mm 18mm 3.00g – 3.50g 4.20g – 4.40g 7.20g – 7.90g 130mm – 160mm 12.0g – 15.0g	Super Plus Applicator 43.0mm – 46.0mm 120mm ± 5% 14.0mm – 15.0mm 18mm 3.00g – 3.50g 4.20g – 4.40g 7.20g – 7.90g 130mm – 160mm 12.0g – 15.0g	Super Plus Applicator 43.0mm – 46.0mm 120mm ± 5% 14.0mm – 15.0mm 18mm 3.00g – 3.50g 4.20g – 4.40g 7.20g – 7.90g 130mm – 160mm 12.0g – 15.0g
Materials <i>Pledget:</i> <i>Withdrawal Cord:</i> <i>Applicator:</i> <i>Individual Wrapping:</i>	All Products 100% Cotton 100% Cotton Polyethylene Polypropylene	All Products 100% Cotton 100% Cotton Polyethylene Polypropylene	All Products 100% Cotton 100% Cotton Polyethylene Cellophane
Additives & Finishing Agents	Hydrophobic coating on withdrawal cord.	Hydrophobic coating on withdrawal cord.	None.

SUMMARY OF NON-CLINICAL DATA:

All materials used in the construction of Tosama 100% Cotton Menstrual Tampons as well as complete devices have been subjected to the following tests in accordance with recommended requirements and proper consideration of its intended use:

- Chemical analysis for pesticide, dioxin, heavy metal, phthalate, and PCB residues;
- Microbiological testing for enumeration per USP <61>/<62>, Toxic Shock Syndrome Toxin-1 production, vaginal microflora growth alteration, and *S. aureus* growth enhancement;
- Biocompatibility testing for *in vitro* cytotoxicity, intracutaneous and vaginal irritation, sensitization, and acute systemic toxicity;
- Efficacy testing for Syngina absorbency, fiber loss, withdrawal cord pull-out resistance, and tampon integrity.

The results of these tests support the conclusion that the proposed device is safe for its intended use.

CONCLUSIONS:

The intended use and indications for use, as well as the safety and effectiveness, of Tosama 100% Cotton Tampons and that of Naturalena and Cottons predicate devices as unscented menstrual tampons are identical. Chemical, biocompatibility, microbiological, and efficacy testing show this to be verifiable. Thus, the Tosama 100% Cotton Tampon is substantially equivalent to the legally marketed predicate devices, Naturalena 100% Cotton Tampon (K130609) and Cottons 100% Natural Cotton Tampon (K080733).