



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 2, 2015

TOSAMA, d.o.o.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K151170
Trade/Device Name: Tosama 100% Organic Cotton Menstrual Tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: June 16, 2015
Received: June 18, 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" (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 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)

K151170

Device Name

Tosama 100% Organic Cotton Menstrual Tampon

Indications for Use (Describe)

The Tosama 100% Organic Cotton Menstrual 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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510(k) Summary

DATE OF PREPARATION: July 1, 2015

COMPANY/OWNER: TOSAMA, d.o.o.
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DEVICE TRADE NAME: Tosama 100% Organic 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 DEVICE: Naturalena 100% Cotton Tampon (K130609)

DEVICE DESCRIPTION: The device will be offered as a traditional unscented menstrual 100% organic 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.

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

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:
The Tosama 100% Organic Cotton Menstrual Tampon demonstrates substantial equivalence to the Naturalena 100% Cotton Tampon (K130609). 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% Organic Cotton Menstrual Tampon	Predicate
		Naturalena 100% Cotton Tampon
510(k) Number		K130609
Intended 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.
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.
Dimensions & Weights	Digital Tampons	Digital Tampons
Description:	Regular Digital	Regular Digital
Length:	43.0mm – 46.0mm	43.0mm – 46.0mm
Diameter:	11.0mm – 12.0mm	11.0mm – 12.0mm
Mass:	2.30g – 2.70g	2.30g – 2.70g
Withdrawal Cord:	130mm – 160mm	130mm – 160mm
Syngina Absorbency:	6.0g – 9.0g	6.0g – 9.0g
Description:	Super Digital	Super Digital
Length:	48.0mm – 51.0mm	48.0mm – 51.0mm
Diameter:	12.0mm – 13.0mm	12.0mm – 13.0mm
Mass:	2.70g – 3.10g	2.70g – 3.10g
Withdrawal Cord:	130mm – 160mm	130mm – 160mm
Syngina Absorbency:	9.0g – 12.0g	9.0g – 12.0g
Description:	Super Plus Digital	Super Plus Digital
Length:	48.0mm – 51.0mm	48.0mm – 51.0mm
Diameter:	14.0mm – 15.0mm	14.0mm – 15.0mm
Mass:	3.30g – 3.80g	3.30g – 3.80g
Withdrawal Cord:	130mm – 160mm	130mm – 160mm
Syngina Absorbency:	12.0g – 15.0g	12.0g – 15.0g
Dimensions & Weights	Applicator Tampons	Applicator Tampons
Description:	Regular Applicator	Regular Applicator
Tampon Length:	43.0mm – 46.0mm	43.0mm – 46.0mm
Applicator Length:	120mm ± 5%	120mm ± 5%
Tampon Diameter:	11.0mm – 12.0mm	11.0mm – 13.0mm
Applicator Diameter:	13mm	16mm
Tampon Mass:	2.00g – 2.30g	2.00g – 2.30g
Applicator Mass:	3.40g – 3.60g	3.40g – 3.60g
Total Mass:	5.40g – 5.90g	5.40g – 5.90g
Withdrawal Cord:	130mm – 160mm	130mm – 160mm

Feature	Tosama 100% Organic Cotton Menstrual Tampon	Predicate
		Naturalena 100% Cotton Tampon
<i>Syngina Absorbency:</i> 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>	6.0g – 9.0g 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	6.0g – 9.0g Super Applicator 48.0mm – 51.0mm 120mm ± 5% 13.0mm – 15.0mm 19mm 2.60g – 3.00g 4.20g – 4.40g 6.80g – 7.40g 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 Not included in submission.
Materials <i>Pledget:</i> <i>Withdrawal Cord:</i> <i>Applicator:</i> <i>Individual Wrapping:</i>	All Products 100% Organic Cotton 100% Organic Cotton TPO Polypropylene	All Products 100% Cotton 100% Cotton Polyethylene Polypropylene
Additives & Finishing Agents	Hydrophobic withdrawal cord.	Hydrophobic coating on withdrawal cord.

The proposed Tosama 100% Organic Cotton Menstrual Tampon and the Naturalena predicate device have the following two differences:

1. Naturalena uses Repellan T anti-wicking agent in its withdrawal cord, while the proposed device uses Sevophob. Both are a paraffin-based resin used to ensure the cord does not wick menstrual fluid out of the vagina.
2. Naturalena uses a polyethylene plastic for the applicator material, while the proposed device uses a thermoplastic olefin plastic for the applicator material.

The proposed device is essentially identical to the Naturalena predicate device other than the differences listed above. It has been demonstrated through biocompatibility and performance testing that neither of the two differences have an impact on the safety and effectiveness of the device. Although the addition of the wicking agent to the withdrawal cord could potentially impact the safety (biocompatibility) of the

device, it has been confirmed as safe through appropriate biocompatibility testing.

SUMMARY OF NON-CLINICAL DATA:

All materials used in the construction of Tosama 100% Organic 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, phthalate, and PCB residues;
- Microbiological testing for enumeration per Ph. Eur. 2.6.12/2.6.13, Toxic Shock Syndrome Toxin-1 production, vaginal microflora growth alteration, and *S. aureus* growth enhancement;
- Biocompatibility testing of the pledget as follows:
 - ISO 10993-5:2009: Tests for *in vitro* cytotoxicity;
 - ISO 10993-10:2010: Tests for irritation and skin sensitization;
 - ISO 10993-11:2006: Tests for systemic toxicity;
- Biocompatibility testing of the applicator as follows:
 - ISO 10993-5:2009: Tests for *in vitro* cytotoxicity;
 - ISO 10993-10:2010: Tests for irritation and skin sensitization;
- Efficacy testing according to the FDA Guidance on Menstrual Tampons and Pads:
 - Syngina absorbency according to 21 CFR 801.430(f)(2);
 - fiber loss;
 - withdrawal cord pull-out resistance;
 - 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% Organic Cotton Menstrual Tampons and that of the Naturalena predicate device as unscented menstrual tampons are identical. Chemical, biocompatibility, microbiological, and efficacy testing show this to be verifiable. Thus, the Tosama 100% Organic Cotton Menstrual Tampon is substantially equivalent to the legally marketed predicate device Naturalena 100% Cotton Tampon (K130609).