February 9, 2018

TOSAMA, d.o.o.
Janez Obreza
Head of Regulatory Affairs
Saranoviceva cesta 35
Vir, SI 1230 Domzale
Slovenia

Re: K172504
Trade/Device Name: Tosama Biobased Applicator Tube Menstrual Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: January 5, 2018
Received: January 11, 2018

Dear Janez Obreza:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172504

Device Name
Tosama Biobased Applicator Tube Menstrual Tampon

Indications for Use *(Describe)*
The Tosama Biobased Applicator Tube 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K172504

DATE OF PREPARATION: February 9, 2018

COMPANY/OWNER: TOSAMA, d.o.o.
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DEVICE TRADE NAME: Tosama Biobased Applicator Tube Menstrual Tampon
COMMON NAME: Unscented Menstrual Tampon
CLASSIFICATION NAME: Tampon, Menstrual, Unscented
REGULATION NUMBER: 21 CFR §884.5470
PRODUCT CODE: HEB (tampon, menstrual, unscented)
DEVICE CLASS: II

PREDICATE DEVICE: Tosama 100% Organic Cotton Menstrual Tampon (K151170)
The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION: The device will be offered as a traditional unscented menstrual tampon consisting of an absorbent pledget, a withdrawal cord, and an applicator comprised of biobased plastic. 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 Biobased Applicator Tube Menstrual Tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.

SUBSTANTIAL EQUIVALENCE DISCUSSION:
The Tosama Biobased Applicator Tube Menstrual Tampon demonstrates substantial equivalence to the Tosama 100% Organic Cotton Menstrual Tampon (K151170).

The table below summarizes the key technological characteristics and features of both the predicate and subject devices.

Feature	**Tosama Biobased Applicator Tube Menstrual Tampon**	**PREDICATE: Tosama 100% Organic Cotton Tampon**
510(k) Number	K172504	K151170
Indication for Use	The Tosama Biobased Applicator Tube Menstrual Tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.	The Tosama 100% Organic Menstrual Tampon 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	***Applicator Tampons***	***Applicator Tampons***
Description:	**Regular Applicator**	**Regular Applicator**
Tampon Length:	43.0mm – 48.0mm	43.0mm – 46.0mm
Applicator Length:	120mm ± 5%	120mm ± 5%
Tampon Diameter:	11.0mm – 14.0mm	11.0mm – 12.0mm
Applicator Diameter:	16mm	13mm
Tampon Mass:	1.50g – 2.30g	2.00g – 2.30g
Applicator Mass:	3.00g – 3.40g	3.40g – 3.60g
Total Mass:	4.50g – 5.70g	5.40g – 5.90g
Withdrawal Cord:	130mm – 160mm	130mm – 160mm
Syngina Absorbency:	6.0g – 9.0g	6.0g – 9.0g
Description:	**Super Applicator**	**Super Applicator**
Tampon Length:	43.0mm – 48.0mm	43.0mm – 46.0mm
Applicator Length:	120mm ± 5%	120mm ± 5%
Tampon Diameter:	13.0mm – 16.0mm	12.0mm – 13.0mm
Applicator Diameter:	18mm	16mm
Tampon Mass:	2.10g – 3.00g	2.60g – 3.00g
Applicator Mass:	3.80g – 4.00g	4.10g – 4.30g
Total Mass:	5.90g – 7.00g	6.70g – 7.30g
Withdrawal Cord:	130mm – 160mm	130mm – 160mm
Syngina Absorbency:	9.0g – 12.0g	9.0g – 12.0g
Description:	**Super Plus Applicator**	**Super Plus Applicator**
Tampon Length:	43.0mm – 48.0mm	43.0mm – 46.0mm
Applicator Length:	120mm ± 5%	120mm ± 5%
Tampon Diameter:	13.0mm – 16.0mm	14.0mm – 15.0mm
Applicator Diameter:	18mm	18mm

Tampon Mass: *Applicator Mass:* *Total Mass:* *Withdrawal Cord:* *Syngina Absorbency:*	3.00g – 4.00g 3.80g – 4.00g 6.80g – 8.00g 130mm – 160mm 12.0g – 15.0g	3.00g – 3.50g 4.20g – 4.40g 7.20g – 7.90g 130mm – 160mm 12.0g – 15.0g
Materials *Pledget:* *Withdrawal Cord:* *Applicator:* *Individual Wrapping:*	*All Products* 100% Organic Cotton 100% Organic Cotton Biobased LDPE Polypropylene	*All Products* 100% Organic Cotton 100% Organic Cotton TPO Polypropylene
Additives & Finishing Agents	Hydrophobic withdrawal cord	Hydrophobic withdrawal cord

The subject and predicate device have the same intended use.

The subject and predicate device have different technological characteristics, namely in dimensions and materials. The material and dimensional changes do not raise different questions of safety or effectiveness.

SUMMARY OF NON-CLINICAL DATA:
All materials used in the construction of Tosama Biobased Applicator Tube 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:

- The proposed device uses identical materials, processes, and equipment for the cotton/pledget and only proposes to change the applicator material component of the device. As such, the testing conducted on the cotton/pledget to support the predicate submission is applicable to the proposed device (e.g., chemical residues, production of toxic shock syndrome toxin, vaginal microflora, and Staphylococcus aureus growth enhancement).
- Biocompatibility testing of the applicator as follows:
  - ISO 10993-5:2009: Tests for *in vitro* cytotoxicity;
  - ISO 10993-10:2010: Tests for irritation and sensitization;
- Microbiological testing on the complete finished device for total aerobic microbial count, total yeast and mold count, and absence of pathogenic organisms (C. albicans, S. aureus, and P. Aeruginosa)
- Testing on each absorbency level of the complete finished device according to the FDA Guidance on Menstrual Tampons and Pads:
  - Syngina absorbency according to 21 CFR 801.430(f)(2);
  - dimensional analysis and mass
  - withdrawal cord pull-out strength;
  - fiber loss;
  - tampon integrity.

The results of these tests met pre-defined acceptance criteria as applicable and are acceptable.

CONCLUSIONS:

The Tosama Biobased Applicator Tube Menstrual Tampon is substantially equivalent to the legally marketed predicate device Tosama 100% Organic Cotton Menstrual Tampon (K151170).