September 30, 2022

Suzhou Borage Medical Technology Co., Ltd.
℅ Grace Liu
Consultant
Shenzhen Joyantech Consulting Co. Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K222046
Trade/Device Name: Unscented Menstrual Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: June 13, 2022
Received: July 11, 2022

Dear Grace Liu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222046

Device Name
Unscented Menstrual Tampon

Indications for Use *(Describe)*
The unscented 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K222046

1. Contact Details

1.1 Applicant information

Applicant Name	Suzhou Borage Medical Technology Co., Ltd.
Address	No.9 Shiheshan Road, Dongshan Town, Wuzhong District, Suzhou City, Jiangsu Province, 215107, China
Contact person	Zhou Nana
Phone No.	+86-512-66280008
E-mail	znn@borage.com.cn
Date Prepared	2022-09-27

1.2 Submission Correspondent

	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86-755-86069197
Contact person	Grace Liu; Field Fu;
Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Unscented Menstrual Tampon
Common name	Unscented Menstrual Tampon
Classification	II
Classification name	Tampon, Menstrual, Unscented
Product code	HEB
Regulation No.	21 CFR 884.5470

3. Legally Marketed Predicate Device

Trade Name	Tosama 100% Organic Cotton Menstrual Tampon
510(k) Number	K15117
Product Code	HEB
Manufacturer	TOSAMA, d.o.o.

The predicate device has not been subject to a design-related recall.

4. Device Description

The proposed device is a traditional unscented menstrual tampon, and it has two types (i.e. digital tampon and applicator tampon). Each device consists of a tampon, including an absorbent pledget ("absorbent core") completely surrounded by overwap ("security veil") and a removal string ("withdrawal cord"), and an applicator (only for the applicator tampon). The tampon is of the traditional cylindrical, bullet-like shape. The applicator

has a smooth, rounded tip to ease insertion.

The proposed device is provided in 4 absorbencies: light (≤6g), regular (6~9g), super (9~12g) and super plus (12~15g). Each device is individually wrapped and packaged in sealed multi-unit containers for retail sale. And it is provided non-sterile and for single use only.

5. Intended Use/Indication for Use

The unscented menstrual tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.

6. Technological Characteristics Comparison

Table 1 Technological Characteristics Comparison Table

Comparison item		Proposed Device (K222046)	Predicate Device (K15117)	Comment
Manufacturer		Suzhou Borage Medical Technology Co., Ltd.	TOSAMA, d.o.o.	None
Product Name		Unscented Menstrual Tampons	Tosama 100% Organic Cotton Menstrual Tampon	None
Product Code		HEB	HEB	Same
Regulation Number		21 CFR § 884.5470	21 CFR § 884.5470	Same
Classification		Class II	Class II	Same
Intended Use/ Indications for Use		The unscented menstrual tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.	The Tosama 100% Organic Cotton Menstrual Tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.	Same
Single Use		Yes	Yes	Same
Sterility		Non-sterile	Non-sterile	Same
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.	Same
Absorbency				
Light		≤6g	N/A	Different
Regular		6~9g	6~9g	
Super		9~12g	9~12g	
Super plus		12~15g	12~15g	
Product dimensions				
Digital tampon				Different
Light	Pledget length	(40~50) mm	N/A	

	Pledget diameter	(9.5~12.5) mm		
	Removal string length	(125~165) mm		
Regular	Pledget length	(40~50) mm	(43.0~46.0) mm	
	Pledget diameter	(10.5~13.5) mm	(11.0~12.0) mm	
	Removal string length	(125~165) mm	(130~160) mm	
Super	Pledget length	(45~55) mm	(48.0~51.0) mm	
	Pledget diameter	(11.5~14.5) mm	(12.0~13.0) mm	
	Removal string length	(125~165) mm	(130~160) mm	
Super plus	Pledget length	(45~55) mm	(48.0~51.0) mm	
	Pledget diameter	(13.3~16.3) mm	(14.0~15.0) mm	
	Removal string length	(125~165) mm	(130~160) mm	
Applicator tampon				
Light	Pledget length	(40~50) mm	N/A	
	Pledget diameter	(9.5~12.5) mm		
	Removal string length	(125~165) mm		
	Applicator length	125 mm		
	Applicator diameter	15 mm		
Regular	Pledget length	(40~50) mm	(43.0~46.0) mm	
	Pledget diameter	(10.5~13.5) mm	(11.0~12.0) mm	
	Removal string length	(125~165) mm	(130~160) mm	
	Applicator length	125 mm	120 mm	
	Applicator diameter	15 mm	13 mm	
Super	Pledget length	(45~55) mm	(43.0~46.0) mm	
	Pledget diameter	(11.5~14.5) mm	(12.0~13.0) mm	
	Removal string length	(125~165) mm	(130~160) mm	
	Applicator length	126 mm	120 mm	
	Applicator diameter	16.5 mm	16 mm	
Super plus	Pledget length	(45~55) mm	(43.0~46.0) mm	
	Pledget diameter	(13.3~16.3) mm	(14.0~15.0) mm	
	Removal string length	(125~165) mm	(130~160) mm	
	Applicator length	126 mm	120 mm	
	Applicator diameter	16.5 mm	18 mm	
Component	Pledget	100% Viscose	100% Organic Cotton	Different

Materials	Overwap	Polyethylene and Polyethyleneterephthalate	100% Organic Cotton	
	Removal string	Polyester and Viscose	100% Organic Cotton	
	Applicator	Polyethylene and Polypropylene	TPO	
Additives and Finishing Agents	Anti-wicking agent of removal string	Paraffin-based resin	Paraffin-based resin	Same
	Finishing agent of pledget	Polyoxyethylene stearate	Not available	Different
Complies with ISO 10993-1		Yes	Yes	Same
Compliance with microbiology requirements of FDA Guidance for Tampons		Yes	Yes	Same
Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

The proposed device has the similar indication for use as the predicate device as well as comparable technical characteristics, and the differences don't raise any additional questions for safety and effectiveness. Therefore, the subject device has the same intended use as the predicate.

7. Summary of Non-clinical Testing

Non-clinical testing was conducted to verify that the proposed device can meet all design specifications and perform similarly to the predicate device. The following tests were conducted.

Performance Testing

The following performance characteristics were assessed in accordance with the FDA guidance document "*Guidance for Industry and FDA Staff - Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)*" issued on July 27, 2005.

- Dimensions
- Absorbency
- Removal string strength
- Fiber shedding
- Tampon integrity
- Chemical residues

All samples met the predefined acceptance criteria.

Biocompatibility Testing

Biocompatibility studies were performed in accordance with the FDA guidance document "*Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process*"' issued on September 4, 2020 as follows:

- In vitro cytotoxicity test per ISO 10993-5:2009
- Skin sensitization test per ISO 10993-10:2010
- Vaginal irritation test per ISO 10993-10:2010
- Acute systemic toxicity test per ISO 10993-11:2017 (tampon only)

All tests were performed on the tampon and applicator separately. The results demonstrated that the proposed device is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Microbiology Testing

Per the FDA guidance document "*Guidance for Industry and FDA Staff - Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)*" issued on July 27, 2005, the following microbiology testing was conducted on the final, finished form of the proposed device, and the test results showed that the proposed device does not:

- enhance the growth of Staphylococcus aureus;
- increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1);
- alter the growth of normal vaginal microflora.

8. Clinical Testing

No clinical study is included in this submission.

9. Conclusions

The nonclinical tests demonstrate that the proposed device is as safe and effective, as the legally marketed device (K15117). Therefore, the subject device is substantially equivalent to the predicate.