May 10, 2024

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

Re: K240708
Trade/Device Name: Organic Cotton Tampon; Organic Cotton PESCVcord Tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: March 6, 2024
Received: March 15, 2024

Dear Liu Grace:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Reginald K. Avery -S

for 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)*
K240708

Device Name
Organic Cotton Tampon;
Organic Cotton PESCVcord Tampon

Indications for Use *(Describe)*
The Organic Cotton Tampon and Organic Cotton PESCVcord Tampon are 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

1. Contact Details

1.1 Applicant information

Applicant Name	Suzhou Borage Medical Technology Co., Ltd.
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Contact person	Zhou Nana
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E-mail	znn@borage.com.cn
Date Prepared	May 9, 2024

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
Contact person's e-mail	grace@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Organic Cotton Tampon Organic Cotton PESCVcord 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	Unscented Menstrual Tampon
510(k) Number	K222046
Product Code	HEB
Manufacturer	Suzhou Borage Medical Technology Co., Ltd.

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

4. Device Description

Organic Cotton Tampon and Organic Cotton PESCVcord Tampon are traditional unscented menstrual tampons. They share the same design and raw materials except the material of the removal strings. Each of them are available in two configurations (i.e., digital tampon and applicator tampon). Each device consists of a tampon,

including an absorbent pledget (“absorbent core”) completely surrounded by an overwrap (“security veil”) and a removal string (“withdrawal cord”), and an applicator (only for the applicator tampon). The tampon design is cylindrical, bullet-like shape. The applicator has a smooth, rounded tip to ease insertion.

Both of Organic Cotton Tampon and Organic Cotton PESCVcord Tampon are provided in 4 absorbency: light (≤6g), regular (6-9g), super (9-12g) and super plus (12-15g). Each device is individually wrapped and then packaged in sealed multi-unit containers for retail sale. All tampons and applicators are provided non-sterile and for single use only.

5. Intended Use/Indication for Use

The organic cotton tampon and the organic cotton PESCVcord tampon are 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	Predicate Device (K222046)
Manufacturer		Suzhou Borage Medical Technology Co., Ltd.	Suzhou Borage Medical Technology Co., Ltd.
Product Name		Organic Cotton Tampon, Organic Cotton PESCVcord Tampon	Unscented Menstrual Tampon
Product Code		HEB	HEB
Regulation Number		21 CFR § 884.5470	21 CFR § 884.5470
Classification		Class II	Class II
Intended Use/ Indications for Use		The organic cotton tampon and the organic cotton PESCVcord tampon are intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.	The tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.
Single Use		Yes	Yes
Sterility		Non-sterile	Non-sterile
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.
Absorbency	Light	≤6g	≤6g
	Regular	6~9g	6~9g
	Super	9~12g	9~12g
	Super plus	12~15g	12~15g

Product dimensions	Digital tampon	Pledget length	Light: 40~50 mm Regular: 40~50 mm Super: 45~55 mm Super plus: 45~55 mm	Light: 40~50 mm Regular: 40~50 mm Super: 45~55 mm Super plus: 45~55 mm
		Pledget diameter	Light: 9.5~12.5 mm Regular: 10.5~13.5 mm Super: 11.5~14.5 mm Super plus: 12.5~15.5 mm	Light: 9.5~12.5 mm Regular: 10.5~13.5 mm Super: 11.5~14.5 mm Super plus: 13.3~16.3 mm
		Removal string length	120~170 mm	125~165 mm
	Applicator tampon	Pledget length	Light: 40~50 mm Regular: 40~50 mm Super: 45~55 mm Super plus: 45~55 mm	Light: 40~50 mm Regular: 40~50 mm Super: 45~55 mm Super plus: 45~55 mm
		Pledget diameter	Light: 9.5~12.5 mm Regular: 10.5~13.5 mm Super: 11.5~14.5 mm Super plus: 12.5~15.5 mm	Light: 9.5~12.5 mm Regular: 10.5~13.5 mm Super: 11.5~14.5 mm Super plus: 13.3~16.3 mm
		Removal string length	120~170 mm	125~165 mm
		Applicator length	Light and Regular: 125 mm Super and Super plus: 126 mm	Light and Regular: 125 mm Super and Super plus: 126 mm
		Applicator diameter	Light and Regular: 15.0 mm Super and Super plus: 16.5 mm	Light and Regular: 15.0 mm Super and Super plus: 16.5 mm
Component Materials	Pledget		100% Organic Cotton	100% Viscose
	Overwap		Polyethylene and Polyethylene terephthalate	Polyethylene and Polyethylene terephthalate
	Removal string		Organic Cotton Tampon: 100% Organic Cotton Organic Cotton PESCVcord Tampon: Polyester and Viscose	Polyester and Viscose
	Applicator		Polyethylene and Polypropylene	Polyethylene and Polypropylene
Additives and Finishing Agents			Paraffin-based resin	Paraffin-based resin and Polyoxyethylene stearate

The proposed devices have the same indications for use as the predicate device as well as similar technical characteristics. The subject device has differences in material composition and some dimensions. The differences don't raise any additional questions for safety and effectiveness.

7. Summary of Non-clinical Testing

Non-clinical testing was conducted to verify that the proposed devices 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 on Organic Cotton Tampon and Organic Cotton PESCVcord Tampon respectively 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 8, 2023.

The following tests were performed on the "tampon" component of Organic Cotton Tampon.

- In vitro cytotoxicity test per ISO 10993-5:2009
- Skin sensitization test per ISO 10993-10:2021
- Vaginal irritation test per ISO 10993-23:2021
- Acute systemic toxicity test per ISO 10993-11:2017

The results demonstrated that the tampon component of Organic Cotton Tampon is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

The only difference between Organic Cotton PESCVcord Tampon and Organic Cotton Tampon is the raw materials of removal strings, while the removal string used in Organic Cotton PESCVcord Tampon is just the same as that used in the predicate device (K222046). So the biocompatibility data of Organic Cotton Tampon and the predicate

device was leveraged to demonstrate the safety of the “tampon” component of Organic Cotton PESCVcord Tampon.

The applicator used in the proposed devices is identical to the applicator used in the predicate device (K222046). Therefore, the biocompatibility data from the predicate device was leveraged to demonstrate the safety of the “applicator” component of the proposed devices.

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 Organic Cotton Tampon, 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.

The only difference between Organic Cotton PESCVcord Tampon and Organic Cotton Tampon is the raw materials of removal strings, while the removal string used in Organic Cotton PESCVcord Tampon is just the same as that used in the predicate device (K222046). So the microbiology testing data of Organic Cotton Tampon and the predicate device was leveraged to demonstrate the microbiology safety of Organic Cotton PESCVcord Tampon.

8. Clinical Testing

No clinical study is included in this submission.

9. Conclusions

The nonclinical tests demonstrate that the proposed devices are as safe and effective as the legally marketed device (K222046). Therefore, the subject devices are substantially equivalent to the predicate device.