August 14, 2023

Zhejiang Tianqing Manufacturing Technology Group 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: K231341
Trade/Device Name: Organic cotton tampon, Viscose tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: August 3, 2023
Received: August 3, 2023

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,

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)*
K231341

Device Name
Organic cotton tampon, Viscose tampon

Indications for Use *(Describe)*
The 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.

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510(k) Summary – K231341

1. Contact Details

1.1 Applicant information

Applicant Name	Zhejiang Tianqing Manufacturing Technology Group Co., Ltd.
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Date Prepared	August 8, 2023

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
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Contact person's e-mail	grace@cefda.com, field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Organic cotton tampon, Viscose 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	K151170
Product Code	HEB
Manufacturer	TOSAMA, d.o.o.
Design Related Recall	None

4. Device Description

The organic cotton tampon and viscose tampon are traditional unscented menstrual tampons. Except for the raw materials, they share the same design. The organic cotton tampon and viscose tampon, both have two types i.e., digital tampon and applicator tampon. The tampon applicator is available in two colors - milky and pink. Each device consists of a tampon, including an absorbent 100% organic cotton or 100% viscose pledget ("absorbent core") surrounded by polyethylene and polyethylene terephthalate

overwrap (“security veil”), a 100% organic cotton or polyester and cotton removal string (“withdrawal cord”), and an applicator (only for the applicator tampon). The applicator is made of polyethylene and polypropylene. The tampon is of the traditional cylindrical, bullet-like shape. The applicator has a smooth, rounded tip to ease insertion.

Both, organic cotton tampon and viscose tampon, are provided in 4 absorbencies: light (≤6g), regular (6~9g), super (9~12g) and super plus (12~15g). Each device is individually wrapped in a polyethylene/nonwoven laminated film or cellophane film and packaged in sealed multi-unit containers for retail sale. It is provided non-sterile and for single use only.

5. Intended Use/Indication for Use

The 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	Subject Device (K231341)		Predicate Device (K151170)	Comment
Manufacturer	Zhejiang Tianqing Manufacturing Technology Group Co., Ltd.		TOSAMA, d.o.o.	None
Product Name	Organic cotton tampon	Viscose tampon	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 tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.		The Tosoma 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	(43~49) mm	N/A	
	Pledget diameter	(9.5~12.5) mm		
	Removal string length	(120~160) mm		
Regular	Pledget length	(44~50) mm	(43.0~46.0) mm	
	Pledget diameter	(10.5~13.5) mm	(11.0~12.0) mm	
	Removal string length	(120~160) mm	(130~160) mm	
Super	Pledget length	(45~51) mm	(48.0~51.0) mm	
	Pledget diameter	(11.5~14.5) mm	(12.0~13.0) mm	
	Removal string length	(120~160) mm	(130~160) mm	
Super plus	Pledget length	(45~51) mm	(48.0~51.0) mm	
	Pledget diameter	(12.5~15.5) mm	(14.0~15.0) mm	
	Removal string length	(120~160) mm	(130~160) mm	
Applicator tampon				
Light	Pledget length	(43~49) mm	N/A	
	Pledget diameter	(9.5~12.5) mm		
	Removal string length	(120~160) mm		
	Applicator length	130.1 mm		
	Applicator diameter	15.2 mm		
Regular	Pledget length	(44~50) mm	(43.0~46.0) mm	
	Pledget diameter	(10.5~13.5) mm	(11.0~12.0) mm	
	Removal string length	(120~160) mm	(130~160) mm	
	Applicator length	130.1 mm	120 mm	
	Applicator diameter	15.2 mm	13 mm	
Super	Pledget length	(45~51) mm	(43.0~46.0) mm	
	Pledget diameter	(11.5~14.5) mm	(12.0~13.0) mm	
	Removal string length	(120~160) mm	(130~160) mm	
	Applicator length	131.0 mm	120 mm	
	Applicator diameter	16.7 mm	16 mm	
Super plus	Pledget length	(45~51) mm	(43.0~46.0) mm	
	Pledget diameter	(12.5~15.5) mm	(14.0~15.0) mm	
	Removal string length	(120~160) mm	(130~160) mm	
	Applicator length	131.0 mm	120 mm	

	Applicator diameter	16.7 mm		18 mm	
Component Materials	Pledget	100% Organic Cotton	100% Viscose	100% Organic Cotton	Different
	Overwrap	Polyethylene and Polyethylene terephthalate	Polyethylene and Polyethylene terephthalate	100% Organic Cotton	
	Removal string	100% Organic Cotton	PolyesterAnd Cotton	100% Organic Cotton	
	Applicator	Polyethylene and Polypropylene	Polyethylene and Polypropylene	TPO	
Additives and Finishing Agents	Anti-wicking agent of removal string	Repellan T	Repellan T	Sevophob	Different
	Finishing agent of pledget	Fiber finishes	Fiber finishes	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 and FDA Menstrual Tampons and Pad guidance		Complied with 21 CFR part 801 and FDA Menstrual Tampons and Pads guidance	Same

The subject devices have the same indication for use as the predicate device; therefore, the subject device has the same intended use as the predicate device. The differences in technological characteristics between the subject and predicate devices, outlined in Table 1, do not raise different questions for safety and effectiveness.

7. Summary of Non-clinical Testing

Non-clinical testing was conducted to verify that the subject devices meet all design and performance specifications similarly to the predicate device. The following tests were conducted.

Performance Testing

The following performance characteristics were assessed on the organic cotton tampon and the viscose tampon 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

Biocompatibility Testing

Biocompatibility studies were performed on the organic cotton tampon and the viscose tampon 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 10993-10:2021
- Vaginal irritation test per ISO 10993-23:2021
- Acute systemic toxicity test per ISO 10993-11:2017 (tampon only)

All the above tests, except acute systemic toxicity, were performed on the applicator. The tampon and applicator were tested separately. The results demonstrated that the subject 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 highest absorbency of the final, finished form of the subject devices (i.e., the organic cotton tampon and the viscose tampon), and the test results showed that the subject devices do not:

- enhance the growth of Staphylococcus aureus;
- increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1); and do not
- 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 (K151170). Therefore, the subject device is substantially equivalent to the predicate device.