January 10, 2025

Shandong Intco Hygiene Products Co., Ltd.
Max Li
QA
Workshop C3, No. 29, Zhangliu Road, Fangzhen Town
Zhangdian DistrictZibo,
Shandong 255000
China

Re: K241064
Trade/Device Name: Unscented Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: December 13, 2024
Received: December 13, 2024

Dear Max Li:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241064

Device Name

Unscented Tampon

Indications for Use *(Describe)*

The Unscented 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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"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

(As requirement by 21 CFR 807.92)

Date prepared: January 9, 2025

A. Applicant:

Name: SHANDONG INTCO HYGIENE PRODUCTS CO., LTD.
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Submission Correspondent:
Primary contact: Maxli
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Email: jiashuangshuang@intco.com

B. Device:

Trade Name: Unscented Tampon
Common Name: Unscented Menstrual Tampon

Regulatory Information
Classification Name: Tampon, Menstrual, Unscented
Classification: Class II
Product code: HEB
Regulation Number: 21 CFR 884.5470
Review Panel: Obstetrics/Gynecology

C. Predicate device:

K231341
Organic cotton tampon, Viscose tampon
Zhejiang Tianqing Manufacturing Technology Group Co., Ltd.
The predicate device has not been subject to a design-related recall.

D. Indications for use of the device:

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

E. Device Description:

The Unscented Tampons are traditional unscented menstrual tampons. Except for the raw materials, they share the same design. The Unscented Tampons are provided with a cardboard applicator tampon. Each device consists of a tampon, including an absorbent 100% organic cotton or 100% viscose pledget , a 100% organic cotton or polyester and cotton removal string ("withdrawal cord"), and a cardboard applicator . The tampon is of the traditional cylindrical, bullet-like shape. The applicator has a smooth, rounded tip to ease insertion.

The Unscented Tampons are provided in 4 absorbencies: light (≤6g), regular (6~9g), super (9~12g) and super plus (12~15g). Each device is individually wrapped. It is provided non-sterile and for single use only.

F. Summary of Technological Characteristics

The Unscented Tampons are compared with the predicate device in terms of intended use, design, material, specifications, and performance.

The following table shows similarities and differences of use, design, and material between the proposed device and the predicate device.

Table 1 General Comparison of Proposed and Predicate Devices

Device	Proposed Device	Predicate Device	Result
510K #	--	K231341	-
Manufacturer	SHANDONG INTCO HYGIENE PRODUCTS CO., LTD.	Zhejiang Tianqing Manufacturing Technology Group Co., Ltd.	
Product Name	Unscented Tampon	Organic cotton tampon / Viscose tampon	-
Product Code	HEB	HEB	Same
Regulation Number	21 CFR 884.5470	21 CFR 884.5470	Same
Classification	Class II	Class II	Same
Indications for use	The Unscented Tampon is 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.	Same
Single use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Design feature	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 Regular: 6~9g Super: 9~12g Super plus: 12~15g	Light: ≤6g Regular: 6~9g Super: 9~12g Super plus: 12~15g	Same

Product dimensions						
Applicator tampon						
Light	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	45 – 50 mm 12.2 – 13.7 mm 115 -175 mm 120 – 125 mm 13.8 – 14.2 mm	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	43~49 mm 9.5~12.5 mm 120~160 mm 130.1 mm 15.2 mm	different	
Regular	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	45 – 50 mm 12.2 – 13.7 mm 115 -175 mm 120 – 125 mm 13.8 – 14.2 mm	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	44~50 mm 10.5~13.5 mm 120~160 mm 130.1 mm 15.2 mm	different	
Super	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	45 – 50 mm 14.2 – 15.7 mm 115 -175 mm 120 – 125 mm 15.8 – 16.2 mm	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	45~51 mm 11.5~14.5 mm 120~160 mm 131.0 mm 16.7 mm	different	
Super plus	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	45 – 50 mm 14.2 – 15.7 mm 115 -175 mm 120 – 125 mm 15.8 – 16.2 mm	Pledget length Pledget diameter Removal string length Applicator length Applicator diameter	45~51 mm 12.5~15.5 mm 120~160 mm 131.0 mm 16.7 mm	different	
Component Materials	Pledget	100% Organic Cotton / 100% Viscose	Pledget	100% Organic Cotton / 100% Viscose	different	
	Overwrap	Polyethylene and Polyethylene terephthalate	Overwrap	Polyethylene and Polyethylene terephthalate		
	Removal string	100% Organic Cotton / Polyester And Cotton	Removal string	100% Organic Cotton / Polyester And Cotton		
	Applicator	Cardboard	Applicator	Polyethylene and Polypropylene		
Additives and Finishing Agents	removal string	Paraffin-based resin	Repellan T		different	
	pledget	Polyoxyethylene stearate	Fiber finishes			

Analysis: 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.

G. 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.

- **Biocompatibility**

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 were performed on the applicator, except acute systemic toxicity. 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.

- **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
- String strength
- Absorbency per Syngyna Testing (21 CFR 801.430)
- Applicator expulsion force
- Appearance
- Applicator and tampon integrity
- Fiber shedding
- Chemical residues

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(K) submission, the Unscented Tampons are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K231341.