August 13, 2025

Unibeauty (Hubei) Technology Co.,Ltd.
% Doris Chen
Regulatory Affairs Specialist
Shanghai Jiushun Enterprise Management Tech. Service Co. Ltd
Room 1502,BaoAn Building,No. 800 Dongfang Road
Shanghai, 200122
CHINA

Re: K251033
Trade/Device Name: Unscented menstrual long applicator tampon;
Unscented menstrual Cardboard Applicator Tampon;
Unscented menstrual Digital Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: July 16, 2025
Received: July 16, 2025

Dear Doris Chen:

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,

Jason Roberts -S

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)*
*K*251033

Device Name
1.Unscented menstrual long applicator tampon
2.Unscented menstrual Cardboard Applicator Tampon
3.Unscented menstrual Digital Tampons

Indications for Use *(Describe)*
The Unscented Menstrual Tampons are inserted into the vagina to absorb menstrual 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 - K251033

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Summary Prepared Date: August 13, 2025

1. Applicant :

- Company Name: Unibeauty (Hubei) Technology Co.,Ltd.
- Address: Building A8,nonwoven small and medium-sized enterprise Industrial Park, PENGCHANG Town, Xiantao City, Hubei Province, China,433018
- Phone:+86-728-8220088
- Contact Person (including title):Guofeng Ou(Manger)

2 Submission Correspondent:

- Contact Person: Doris Chen
- Shanghai Jiushun Enterprise Management Technology Service Co., Ltd.
- Address: Room 1502,BaoAn Buiding,No.800 Dongfang Road, Shanghai, China.
- Tel: +86-21-50931939
- Email: doris-chen@isosh.com

3 Subject Device Information:

- Common Name: Unscented Menstrual Tampon
- Trade Name: 1.Unscented menstrual long Applicator Tampon
  2.Unscented menstrual Cardboard Applicator Tampon
  3.Unscented menstrual Digital Tampons
- Classification Name: Tampon, Menstrual, Unscented
- Product Code: HEB
- Regulation Number:21 CFR 884.5470
- Regulation Class: II

4 Predicate Device Information:

- Sponsor: Unibeauty (Hubei) Technology Co.,Ltd.
- Common Name: Unscented Menstrual Tampon
- Trade Name: Unscented Menstrual Tampon

- 510(k) number: K232598
- Classification Name: Tampon, Menstrual, Unscented
- Product Code: HEB
- Regulation Number:21 CFR 884.5470
- Regulation Class: II

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

5.Device Description

The unscented menstrual tampons consist 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.

According to different composition materials and design styles, the unscented menstrual tampons of this submission are divided into 3 categories (Unscented menstrual long applicator tampon, Unscented menstrual Cardboard Applicator Tampon, Unscented menstrual Digital Tampons) and 6 sub-categories (Organic cotton + Two Plastic tube, Cotton + cardboard tube, Organic cotton + cardboard tube, Cotton (digital style), Organic cotton(digital style), viscose(digital style).

The tampons are provided in 4 absorbencies: Light(L) (≤6g), Regular(R) (6-9g), Super (S)(9-12g) and Super Plus (SP)(12-15g). Only some sub-categories of tampons contain all absorbencies.

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.

Please refer to the product comparison table and product photos for specific composition materials and model specification.

6.0 Comparison of Technological Characteristics with the Predicate Device

The following table compares the Unscented Menstrual Tampon to the predicate devices (K232598) with respect to intended use, technological characteristics, and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

6.1 Comparison Table of Technological Characteristic with the Predicate Device

Technological Characteristics Comparison Table

Elements of Comparison	**Subject Device**			**Predicate Device**	**Verdict**
Device Trade Name	Unscented menstrual long Applicator Tampon	Unscented menstrual Cardboard Applicator Tampon	Unscented menstrual Digital Tampons	Unscented Menstrual Tampon	--
Manufacturer	Unibeauty (Hubei) Technology Co.,Ltd.			Unibeauty (Hubei) Technology Co.,Ltd.	--
K Number	K251033			K232598	--
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 Menstrual Tampons are inserted into the vagina to absorb menstrual discharge.			The Unscented Menstrual Tampons are inserted into the vagina to absorb menstrual discharge.	Same
Sterile	No			No	Same
Single-Use	Yes			Yes	Same
Design	Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.		Tampon with cylindrical shape and bullet-like tip. Digital tampon without applicator.	Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.	Similar
Unscented/ Scented	Unscented			Unscented	Same
Dimensions Specifications (mm)	Pledget length (Dry): 37±3.0--50±3.0 Pledget diameter(Dry):	Pledget length (Dry): 37±3.0--50±3.0 Pledget diameter(Dry):	Pledget length (Dry): Viscose core: 43±5.0mm-50±5.0	Total length of the Product:122.2±1.5	Different

Technological Characteristics Comparison Table

Elements of Comparison	**Subject Device**			**Predicate Device**	**Verdict**
Device Trade Name	Unscented menstrual long Applicator Tampon	Unscented menstrual Cardboard Applicator Tampon	Unscented menstrual Digital Tampons	Unscented Menstrual Tampon	--
	11.5±1.0--15.2±1.0 Total length of the product:118.0±2.0 Length of the push rod on product:70±1 Outside diameter (outer tube): 14.5±0.2--16.2±0.2	11.5±1.0--15.2±1.0 Total length of the product:122.5±2.0 Length of the push rod on product:67±1 Outside diameter (outer tube): 14.1±0.2--16.1±0.2	organic cotton core and cotton core: 38.5±5.0mm-50±5.0 Pledget diameter(Dry): 12.5±0.2--15.2±0.2	Length of the push rod on product:70±1 Outside diameter (outer tube): 14.5±0.2--16.2±0.2	
Weight Specifications(g) (without single wrapper)	L: 3.90-4.40g R: 4.45-5.15g S: 5.65-6.45g SP: 6.45-7.35g	R: 3.90-4.60g S: 4.90-5.70g	viscose core: R: 1.70-2.30g S: 2.40-3.10g SP: 3.00-3.60g organic cotton core & cotton core: R: 1.95-2.55g S: 2.50-3.30g SP: 3.30-4.10g	L: 4.55±0.30g R :5.10±0.30g S :5.90±0.35g SP: 6.45±0.35g	Different
Absorbent Pledget	Organic cotton	Organic cotton and Cotton	Organic cotton , Cotton, and Viscose	Viscose and Cotton	Similar
Overwrap	Organic cotton	Organic cotton and Cotton	Organic cotton , Cotton, and Viscose	PE+PP	Different
Removal string	Organic cotton	Organic cotton and Cotton	Organic cotton and Cotton	Cotton and Polypropylene	Different

Technological Characteristics Comparison Table

Elements of Comparison	**Subject Device**			**Predicate Device**	**Verdict**
Device Trade Name	Unscented menstrual long Applicator Tampon	Unscented menstrual Cardboard Applicator Tampon	Unscented menstrual Digital Tampons	Unscented Menstrual Tampon	--
Applicator	LDPE	Cardboard	None	LDPE	Different
Absorbencies	L:≤6g R: 6-9g S: 9-12g SP: 12-15g	R: 6-9g S: 9-12g	R: 6-9g S: 9-12g SP: 12-15g	L:≤6g R: 6-9g S: 9-12g SP: 12-15g	Similar
Primary packaging	Paper/PE	Paper/PE	PET+CPP	individual polymeric wrapper	Different
The subject device has the similar indication for use as the predicate device as well as comparable technological characteristics. The differences include the material composition and dimensions; however, the differences do not raise different questions of safety and effectiveness.					

Note 1:LDPE(Low-Density Polyethylene),PET(Polyethylene terephthalate),CPP(Polypropylene),PE(Polyethylene)

The subject device and predicate device are similar in the pledget composition and components (tampon and applicator). The subject and predicate device differ in the tampon and applicator materials, available absorbencies, as well as the tampon and applicator design.

Note 2: The unscented menstrual tampon (Unscented menstrual long applicator tampon, Unscented menstrual Cardboard Applicator Tampon, Unscented menstrual Digital Tampons) have new dimensional and weight specifications as compared to the predicate device. The subject device has an organic cotton absorbent pledget that differs from the predicate's cotton and viscose blended pledget. In addition to plastic(low density polyethylene) applicator, the cardboard applicator version of the device differs in applicator material compared to the predicate. The digital tampon without applicator is an additional version not available with the predicate. Other design and material specifications remain identical to predicate device.

7.Substantial Equivalence Discussion

Technical Equivalence

Technical equivalence is determined by means of the condition for use, specification, design, deployment method and principle of operation.

Subject devices differ slightly from predicate devices in technical characteristics due to changes in raw materials and design styles, such as weight and dimensional specifications. However, these differences do not raise different questions of safety and effectiveness.

Biocompatibility Assessment

Biocompatibility studies were performed in accordance with the FDA guidance document "Guidance for industry and Food and Drug Administration Staff - Use of International Standard 1S0 10993-1, "Biological Evaluation of Medical Devices - Part 1:Evaluation and testing within a risk management process" issued on September 8, 2023.

The following assessment were performed on the "tampon" component of organic cotton tampon.

No.	FDA recognition number	Standards Development Organization (SDO), Designation Number-Year, and Title
1	2-258	ISO 10993-1: 2018 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process
2	2-245	ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
3	2-174	ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

4	2-291	ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Tests for irritation
5	2-255	IS0 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Pledget

The materials in the absorbent pledget of the predicate (K232598) is the same as the absorbent pledget material of several models of subject device submitted in this 510(k) (e.g. Cotton + cardboard tube, Cotton (digital style), viscose(digital style)). Therefore, the biocompatibility data from the predicate device was leveraged to demonstrate the safety of the "absorbent pledget" component of the proposed device versions. The biocompatibility evaluation of the organic cotton tampons demonstrates the subject device (organic cotton tampon) and the predicate device are equally safe and effective in terms of biocompatibility.

Applicator

For the applicator made of Plastic, the material of the subject device and the predicate device applicator is identical. Therefore, the biocompatibility data from the predicate device was leveraged to demonstrate the biocompatibility of the "applicator" component of the proposed devices.

For the applicator made of cardboard, biocompatibility testing was conducted, including in vitro cytotoxicity, sensitization, and irritation tests, as seen below.

No.	FDA recognition number	Standards Development Organization (SDO), Designation Number-Year, and Title
1	2-258	ISO 10993-1: 2018 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process
2	2-245	ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
3	2-174	ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
4	2-291	ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Tests for irritation

Result

The test results show that the cardboard applicator has no cytotoxicity, no sensitization, and no irritation.

Microbiology Assessment

• 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 cotton and viscose version of the tampon are composed of the same raw material as the predicate device (K232598). However, the organic cotton tampon is made with a different material. Therefore, microbiology testing was conducted on the Organic Cotton Tampon. While the microbiology testing of the predicate device was leveraged to demonstrate the microbiological safety of the cotton and viscose versions of this device.

Chemical Residue Assessment

Chemical residue assessment of tampons was conducted in accordance with the requirements set forth in the guidance document “Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff” dated July 2005.

The pledget version made of cotton and viscose is identical to the predicate device(K232598). Chemical residue testing was conducted on the Organic Cotton Tampon. While the chemical residue testing of the predicate device was leveraged to demonstrate the absence of harmful chemicals in the cotton and viscose version of this device.

For the absorbent pledget made of organic cotton, chemical residue tests have been carried out and the tests show that the subject device does not:

• 2.3.7.8- tetrachlorodibenzo-p-dioxin(TCDD)

• 2.3.7.8-tetrachlorofuran dioxin (TCDF)

• Pesticide and herbicide residues

8. Summary Of Verification And Validation

Non-clinical performance testing was performed based on a risk assessment utilizing Failure Mode Effect Analysis (FMEA).

Following Quality System processes, required testing was conducted to validate the cumulative modifications made to the subject devices. Based on the risk analysis, there is an identification of the verification and/or validation activities required to comply with 21 CFR 820.30.

Performance testing was used for verification and/or validation activities as noted above.

9.Conclusion

The nonclinical tests demonstrate that the subject device, Unscented Menstrual Tampon, is as safe and effective as the legally marketed predicate device (K232598). Therefore, the subject device is substantially equivalent to the predicate device.