December 17, 2025

Unibeauty (Hubei) Technology Co., Ltd.
Sandra Jiang
RA Manager
Bldg. A8, Nonwoven Small And Medium-Sized Enterprise
Industrial Park, Pengchang Town
Xiantao, Hubei
CHINA

Re: K253719
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: November 24, 2025
Received: November 24, 2025

Dear Sandra Jiang:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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)*
K253719

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

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: October 28, 2025

**I. Submitter's Identification**

Submitter Name: Unibeauty (Hubei) Technology Co.,Ltd.
Address: Building A8, nonwoven small and medium-sized enterprise Industrial Park, PENGCHANG Town, Xiantao City, Hubei Province, China
Contacted Person: Guan Zhou
Telephone Number: +86 13560898147
E-mail: guanzhou@uni-beauty.com
Date of Preparation: October 7, 2025

**II. Identification of the device**

**Subject Device**

Common Name: Unscented Menstrual Tampon
Trade Name:

- Unscented Menstrual Long Applicator Tampon
- Unscented Menstrual Cardboard Applicator Tampon
- Unscented Menstrual Digital Tampons

Classification Name: Tampon, Menstrual, Unscented
Product Code: HEB
Regulation: 21 CFR 884.5470
Device Class: II

**Predicate Device**

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

- Unscented Menstrual Long Applicator Tampon
- Unscented Menstrual Cardboard Applicator Tampon
- Unscented Menstrual Digital Tampons

Classification Name: Tampon, Menstrual, Unscented
Product Code: HEB
Regulation: 21 CFR 884.5470
Device Class: II
510k Number: K251033

**III．Reason of submission**

1) Device size change;
2) Device design change

**IV. Device Description**

The proposed unscented menstrual tampons are cylindrical devices designed to absorb menstrual blood during a women's period. They 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 (except for the digital style). The tampon design is cylindrical, bullet-like shape. The applicator has a smooth, rounded tip for ease of 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 7 sub-categories (Cotton + cardboard tube, Organic cotton + cardboard tube, Cotton (digital style), Organic cotton(digital style), viscose (digital style), Cotton + plastic tube and Viscose + cardboard tube). For applicator-style tampons, they feature a built-in applicator made of plastic or cardboard that helps the users insert the tampons into the vagina by pushing the tampon out of the applicator. The digital style tampons consist of a plain tampon designed to be inserted manually using the fingers.

The tampons are provided in 4 absorbencies: Light(L) (≤6g), Regular(R) (6-9g), Super (S)(9-12g) and Super Plus (SP)(12-15g). For Cotton + cardboard tube and Organic cotton + cardboard tube, L and SP are applicable for this application. For Cotton (digital style), Organic cotton (digital style) and Viscose (digital style), only L is applicable. For Cotton + plastic tube and Viscose + cardboard tube, all those four absorbencies are applicable for this application.

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.

| **Category** | **Subcategory** | **Size** | | | |
|---|---|---|---|---|---|
| | | **Light** | **Regular** | **Super** | **Super Plus** |
| Unscented Menstrual Cardboard Applicator Tampon | Cotton + cardboard tube | √ | | | √ |
| | Organic cotton + cardboard tube | √ | | | √ |
| | Viscose + cardboard tube | √ | √ | √ | √ |
| Unscented Menstrual Digital Tampons | Cotton （digital style） | √ | | | |
| | Organic cotton （digital style） | √ | | | |
| | Viscose （digital style） | √ | | | |
| Unscented Menstrual Long Applicator Tampon | Cotton + plastic tube | √ | √ | √ | √ |

**V. Indication for use**

The Unscented Menstrual Tampons are inserted into the vagina to absorb menstrual discharge.

**VI. Technological Characteristics Comparison**

Sponsor: Unibeauty (Hubei) Technology Co.,Ltd.
Subject Device: Unscented Menstrual Tampon

**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 Long Applicator Tampon | Unscented Menstrual Cardboard Applicator Tampon | Unscented Menstrual Digital Tampons | Same |
| Manufacturer | Unibeauty (Hubei) Technology Co.,Ltd. | | | Unibeauty (Hubei) Technology Co.,Ltd. | | | Same |
| K Number | K253719 | | | K251033 | | | -- |
| 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. | | Tampon with cylindrical shape and bullet-like tip. Digital tampon without applicator. | Same |
| Unscented/ Scented | Unscented | | | Unscented | | | Same |

Sponsor: Unibeauty (Hubei) Technology Co.,Ltd.
Subject Device: Unscented Menstrual Tampon

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Dimensions Specifications (mm) | Pledget length (Dry): 35±5.0--50±5.0mm<br>Pledget diameter(Dry): 11.5±2.0--15.2±2.0mm<br>Total length of the product:120.0±4.0--122.2±4.0mm<br>Length of the push rod on product:70±2.0mm<br>Outside diameter (outer tube): 14.5±1.0--16.2±1.0mm | Pledget length (Dry): 35±5.0--50±5.0mm<br>Pledget diameter(Dry): 11.5±2.0--15.2±2.0mm<br>Total length of the product:122.5±4.0mm<br>Length of the push rod on product:67±2.0mm<br>Outside diameter (outer tube): 14.1±1.0--16.1±1.0mm | Pledget length (Dry): 35±5.0mm<br>Pledget diameter(Dry): 11.5±2.0mm | Pledget length (Dry): 37±3.0--50±3.0<br>Pledget diameter(Dry): 11.5±1.0--15.2±1.0<br>Total length of the product:118.0±2.0<br>Length of the push rod on product:70±1<br>Outside diameter (outer tube): 14.5±0.2--16.2±0.2 | Pledget length (Dry): 37±3.0--50±3.0<br>Pledget diameter(Dry): 11.5±1.0--15.2±1.0<br>Total length of the product:122.5±2.0<br>Length of the push rod on product:67±1<br>Outside diameter (outer tube): 14.1±0.2--16.1±0.2 | Pledget length (Dry): Viscose core: 43±5.0mm- 50±5.0<br>organic cotton core and cotton core: 38.5±5.0mm-50±5.0<br>Pledget diameter(Dry): 12.5±0.2--15.2±0.2 | Different |
| Weight Specifications(g) (without single wrapper) | L: 4.00-4.60g<br>R: 4.60-5.40g<br>S: 5.40-6.70g<br>SP: 6.60-7.60g | L: 3.00-3.90g<br>R: 3.90-4.60g<br>S: 4.60-5.70g<br>SP: 5.60-6.70g | Viscose core, organic cotton core and cotton core:<br>L: 1.00-1.70g | L: 3.90-4.40g<br>R: 4.45-5.15g<br>S: 5.65-6.45g<br>SP: 6.45-7.35g | R: 3.90-4.60g<br>S: 4.90-5.70g | viscose core:<br>R: 1.70-2.30g<br>S: 2.40-3.10g<br>SP: 3.00-3.60g<br>organic cotton core & cotton core:<br>R: 1.95-2.55g<br>S: 2.50-3.30g<br>SP: 3.30-4.10g | Different |

Sponsor: Unibeauty (Hubei) Technology Co.,Ltd.
Subject Device: Unscented Menstrual Tampon

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Absorbent Pledget | Cotton | Organic cotton , Cotton, and Viscose | Organic cotton , Cotton, and Viscose | Organic cotton | Organic cotton and Cotton | Organic cotton , Cotton, and Viscose | Similar |
| Overwrap | Cotton | **Viscose:** Spunbond/thermal-bonded nonwoven fabric/cotton **Organic cotton type:** Organic cotton **Cotton type:** Cotton | **Viscose:** Spunbond/thermal-bonded nonwoven fabric/cotton **Organic cotton type:** Organic cotton **Cotton type:** Cotton | Organic cotton | Organic cotton and Cotton | Organic cotton , Cotton, and Viscose | Different |
| Removal String | Cotton | Organic cotton and Cotton | Organic cotton and Cotton | Organic cotton | Organic cotton and Cotton | Organic cotton and Cotton | Similar |
| Applicator | PE | Cardboard | None | LDPE | Cardboard | None | Similar |
| Absorbencies | L:≤6g<br>R: 6-9g<br>S: 9-12g<br>SP: 12-15g | L:≤6g<br>R: 6-9g<br>S: 9-12g<br>SP: 12-15g | L:≤6g | L:≤6g<br>R: 6-9g<br>S: 9-12g<br>SP: 12-15g | R: 6-9g<br>S: 9-12g | R: 6-9g<br>S: 9-12g<br>SP: 12-15g | Same |
| Primary Packaging | Paper/PE/PP | Paper/PE/PP | PET+CPP/paper | Paper/PE | Paper/PE | PET+CPP | Similar |

Sponsor: Unibeauty (Hubei) Technology Co.,Ltd.
Subject Device: Unscented Menstrual Tampon

| |
|---|
| 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. |

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 combination method of pledge and applicator, and available absorbencies.

For Unscented Menstrual Long Applicator Tampon: pledget material was changed from organic cotton to cotton; All the other materials remain the same.

For Unscented Menstrual Cardboard Applicator Tampon: Absorbency options L (Light) and SP (Super Plus) have been added to the Cotton + cardboard tube and Organic cotton + cardboard tube subcategories. Additionally, viscose has been added as a pledget material with all absorbencies (L, R, S, and SP) offered.

For Unscented Menstrual Digital Tampons: Absorbency option L (Light) has been added to the Cotton (digital style), Organic cotton (digital style), and Viscose (digital style) subcategories.

The unscented menstrual tampon (including versions with long applicators, cardboard applicators, and digital tampons) has been updated with new sizes and pledget materials, resulting in slight changes to dimensional and weight specifications compared to the predicate device.
While the method of combining the pledget and applicator differs slightly from that of the predicate device, the materials used remain consistent. The absorbent pledget is made of cotton, organic cotton, or viscose; the overwrap consists of cotton (for cotton type) or organic cotton (for organic cotton type), or Spunbond/thermal-bonded nonwoven fabric/cotton (for Viscose type); the removal string is made of cotton or organic cotton; and the applicator is composed of cardboard or PE.

In summary, the device is substantially equivalent to the predicate devices in terms of features, design, specifications, mode of operation, and intended use. The noted differences do not raise any new safety or effectiveness concerns.

**VII. 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 the combinations of pledget and applicators, and the addition of new absorbencies that impact the 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 material of the proposed device is identical to the predicate device (K251033), and K232598 and K252613 (i.e. the absorbent pledget is made of organic cotton , cotton, and viscose, the applicator is made of cardboard and PE, overwrap and removal string are made of cotton, organic cotton and Spunbond/thermal-bonded nonwoven fabric/cotton). Therefore, biocompatibility test data from the predicate device, K232598 and K252613 were leveraged to demonstrate the safety of the material of the proposed device.

**Microbiology Assessment**

Per the FDA guidance “Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff”, menstrual tampons should demonstrate that the tampon, in its final manufactured form, 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 proposed Unscented Menstrual Tampon (Unscented Menstrual Long Applicator Tampon, Unscented Menstrual Cardboard Applicator Tampon, Unscented Menstrual Digital Tampons) are composed of the same raw material as devices cleared in K232598, K252613 and the predicate (K251033). The microbiology test data from the tampons cleared in the predicate device and K232598 were leveraged to demonstrate the microbiological safety of the tampons used with the applicator introduced in the current submission

**Chemical Residue Assessment**
Chemical residue assessment of tampons is conducted in accordance with the recommendations outlined 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 tampons listed as compatible with the subject device applicator are identical to the predicate device (K251033), and K232598. Chemical residue testing of the predicate device and K232598 were leveraged to demonstrate the absence of harmful chemicals in the cotton and viscose versions of this device.

**VIII. Summary of Verification and Validation:**
In light of the new absorbency levels introduced, non-clinical performance testing was conducted across all product variants: Unscented Menstrual Long Applicator Tampon, Unscented Menstrual Cardboard Applicator Tampon, and Unscented Menstrual Digital Tampons. Test results confirmed that all devices meet the required performance standards.
In accordance with Quality System procedures, all necessary testing was performed to validate

the cumulative modifications to the subject devices. A risk analysis was carried out to identify the verification and validation activities required under 21 CFR 820.30.

**IX. Conclusion**

The nonclinical tests demonstrate that the subject device, Unscented Menstrual Tampon, is as safe and effective as the legally marketed predicate device (K251033). Therefore, the subject device is substantially equivalent to the predicate device.