December 15, 2023

Unibeauty (Hubei) Technology Co.,Ltd.
% Helen Nan
Official Correpondent
New Risen Enterprise Management Consulting Co., Ltd.
Room 302, Building 3, Hangqian Mansion, Hangqian Street
Lucheng District
Wenzhou, Zhejiang 325000
China

Re: K232598
Trade/Device Name: Unscented Menstrual Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: November 13, 2023
Received: November 13, 2023

Dear Helen Nan:

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)*
K232598

Device Name
Unscented Menstrual Tampon

Indications for Use *(Describe)*
The Unscented Menstrual Tampon is 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.

1.0 Submitter Information

- Company: **Unibeauty (Hubei) Technology Co.,Ltd.**
- Address: **Building A8, nonwoven small and medium-sized enterprise Industrial Park, PENGCHANG Town, Xiantao City, Hubei Province**
- Phone: 086-728-8220088
- Contact: Mr. Lin Fongshun, General Manager
- Date Prepared: December 5, 2023

2.0 Device Information

Trade/Device Name: Unscented Menstrual Tampon
Common Name: Unscented Menstrual Tampon
Classification Name: Tampon, Menstrual, Unscented
Classification Regulation: 21 CFR 884.5470
Product Code: HEB (Tampon, Menstrual, Unscented)
Device Class: II

3.0 Predicate Device Information

The predicate device is Ontex Unscented Tampons with Colored Plastic Applicator manufactured by ONTEX BVBA.

510K Number: K142786

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

4.0 Device Description

The Unscented Menstrual Tampons are menstrual tampons used to absorb menstrual fluid. These tampons are provided in 4 absorbencies,

light (≤ 6 grams absorbency), regular (6-9 grams), super (9-12 grams) and super plus (12-15 grams). These tampons include a pledget made from viscose and cotton as well as a polyester and polypropylene overwrap. The removal string is made of polypropylene yarn and cotton yarn. The applicator tubes are made of low density polyethylene (LDPE). The assembled tampon with applicator is wrapped in a printed polyethylene wrapper.

5.0 Indications for Use

The Unscented Menstrual Tampon is inserted into the vagina to absorb menstrual discharge.

6.0 Comparison of Technological Characteristics with the Predicate Device

The following table compares the Unscented Menstrual Tampon to the predicate devices 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

Characteristics	**Subject Device**	**Predicate Device** (K142786)	**Significant Differences**
Device Name	Unscented Menstrual Tampon	Ontex Unscented Tampons with Colored Plastic Applicators	N/A
Regulation Name	Unscented Menstrual Tampon	Unscented Menstrual Tampon	Same
Manufacturer	Unibeauty (Hubei) Technology Co.,Ltd.	ONTEX	N/A

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 Ontex Unscented Tampons with Colored Plastic Applicators are inserted into the vagina to absorb menstrual discharge.	Same
Overall Design	W wadding tampon with plastic applicators of full size (long)	W wadding tampon with plastic applicators of full size (long) and compact size	Different, no compact size
Unscented/Scented	Unscented	Unscented	Same
Dimensions Specifications (mm)	Total length (in ready to push position): 106-122.2 Outside diameter (outer tube): 14.5- 16.2	Total length (in ready to push position): 110 - 135 Outside diameter (outer tube): 13.5 - 18.2	Different
Weight Specifications (g)	4.55-6.45（without single wrapper)	3.6-8.1	Different
Absorbent Pledget	Viscose and Cotton	Viscose	Different
Withdrawal Cord	Cotton and Polypropylene	Cotton polyester	Different
Applicator	Plastic –polyethylene including pigments	Plastic –polyethylene including pigments	Same
Absorbencies	≤6g, 6-9g, 9-12g, 12-15g	<6g, 6-9g, 9-12g, 12-15g	Similar
Expulsion Force	≤7.0N	<6N	Different

Fiber Shedding	<1mg	<1mg	Same
Packaging	Primary packaging: individual polymeric wrapper Secondary packaging: cardboard box	Primary packaging: individual polymeric wrapper Secondary packaging: cardboard box	Same
Sterile	no	no	Same
Single-Use	yes	yes	Same
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.			

7.Performance Testing – Bench

The following performance characteristics were assessed in accordance with the 2005 FDA guidance document *"Guidance for Industry and FDA Staff - Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)"*

- Dimensional information
- Absorbency range, tested using the Syngyna method (per 21 CFR 801.430)
- Chemical residues
- Withdrawal cord strength
- Fiber shedding
- Tampon integrity

The performance tests were conducted to demonstrate the effectiveness of the subject device; all samples met the predefined acceptance criteria.

8.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 4, 2020 as follows:

- In vitro cytotoxicity test per ISO 10993-5:2009 (tampon and applicator)
- Sensitization test per ISO 10993-10:2021 (tampon and applicator)
- Vaginal irritation test per ISO 10993-23:2021 (tampon and applicator)
- Acute systemic toxicity test per ISO 10993-11:2017 (tampon only)

All tests were performed on the tampon and applicator separately. The results demonstrated that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

9.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, microbiology testing was conducted on the final, finished form of the subject device, and the test results showed that the subject 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.

10.Clinical Testing

No clinical study is included in this submission.

11. Conclusions

The nonclinical tests demonstrate that the subject device, Unscented Menstrual Tampon, is as safe and effective, as the legally marketed predicate device (K142786). Therefore, the subject device is substantially equivalent to the predicate device.