April 1, 2025

Essity Higiene Y Salud Mexico. S.A. DE C.V.
% Natalie Kennel
Regulatory Affairs Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K242105
Trade/Device Name: SABA® Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: July 16, 2024
Received: July 18, 2024

Dear Natalie Kennel:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242105

Device Name

SABA® Tampons

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.

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

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510(k) Summary

Sponsor: Essity Higiene Y Salud Mexico
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Ciudad De Mexico, MX CP 05348

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Date Prepared: March 24, 2025

DEVICE INFORMATION:

Proprietary Name: SABA® Tampons
Common Name: Unscented Menstrual Tampon
Classification: Class II
Product Codes: HEB
Regulations: 21 CFR § 884.5470

PREDICATE DEVICE INFORMATIONS

The predicate device is the Organic cotton tampon, Viscose tampon (K231341). This predicate device has not been subject to a design-related recall.

PRODUCT DESCRIPTION:

The SABA® Tampons are traditional unscented menstrual tampons. The SABA® Tampons are available either with a single use applicator or as a digital tampon (without an applicator). Except for the inclusion of the applicator, both types of tampons are made of the same materials. Each device consists of a tampon, including a 100% viscose pledget ("absorbent core") surrounded by a non-woven fabric cover blend of polyethylene and polyester, a removal cord of 67% polyester/33% viscose, and an applicator (only for the applicator tampon). The applicator is made of an inner tube of high-density polypropylene and an external tube of low-density

polyethylene, both with 5% pink pigment. The applicator has a smooth, rounded tip to ease insertion.

Both the applicator and applicator free SABA® Tampons are provided in three absorbencies of regular (6-9g), super (9-12g), and super plus (12-15g). Each device is individually wrapped in a metallized printed bi-oriented polypropylene lamination and packaged in sealed multi-unit containers for retail sale. It is provided non-sterile and for single use only.

INDICATIONS FOR USE:

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

TECHNICOLOGICAL CHARACTERTISTICS COMPARISON:

Below is a detailed comparison of the SABA® Tampons characteristics to the predicate device, K231341. The results of the comparison are displayed in Table 1. The far-right column in the table has the comment about the comparison.

Table 1 Technological Characteristics Comparison Table

Comparison Item	Subject Device	Predicate Device (K231341)		Comment
Manufacturer	Essity Higiene Y Salud Mexico	Zhejiang Tianqing Manufacturing Technology Group Co., Ltd.		None
Product Name	SABA® Tampons	Viscose tampon	Organic cotton 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 absorption of menstrual or other vaginal discharge.	The tampon is intended for insertion into the vagina for 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	N/A	≤6 g		Different
Regular	6~9g	6~9g		
Super	9~12g	9~12g		
Super plus	12~15g	12~15g		
Digital tampon (Applicator Free)				

Comparison Item		Subject Device	Predicate Device (K231341)	Comment
Light	Pledget length	N/A	(43~49) mm	Different
	Pledget diameter		(9.5~12.5) mm	
	Removal String length		(120~160) mm	
Regular	Pledget length	(44~48) mm	(44~50) mm	Similar
	Pledget diameter	(11.5~12.5) mm	(10.5~13.5) mm	Similar
	Removal String length	(110~140) mm	(120~160) mm	Similar
Super	Pledget length	(47~51) mm	(45~51) mm	Similar
	Pledget diameter	(11.8~12.8) mm	(11.5~14.5) mm	
	Removal String length	(105~135) mm	(120~160) mm	
Super plus	Pledget length	(48~52) mm	(45~51) mm	Similar
	Pledget diameter	(13.5~14.5) mm	(12.5~15.5) mm	
	Removal String length	(105~135) mm	(120~160) mm	
Applicator tampon				
Light	Pledget length	N/A	(43~49) mm	Different
	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	(44~48) mm	(44~50) mm	Similar
	Pledget diameter	(11.5~12.5) mm	(10.5~13.5) mm	
	Removal String length	(110~140) mm	(120~160) mm	
	Applicator length	Inner Tube: (71.47~71.97) mm Outer Tuber: (66.81~67.31) mm	130.1 mm	

Comparison Item		Subject Device	Predicate Device (K231341)		Comment
	Applicator diameter (OT)	(15.55~16.15)mm	15.2 mm		
Super	Pledget length	(47~51) mm	(45~51) mm		Similar
	Pledget diameter	(11.8~12.8) mm	(11.5~14.5) mm		
	Removal String length	(105~135) mm	(120~160) mm		
	Applicator length	Inner Tube: (71.47~71.97) mm Outer Tube: (66.81~67.31) mm	131.0 mm		
	Applicator diameter	Outer Tube: (14.40~15.20) mm	16.7 mm		
Super plus	Pledget length	(48~52) mm	(45~51) mm		Similar
	Pledget diameter	(13.5~14.5) mm	(12.5~15.5) mm		
	Removal String length	(105~135) mm	(120~160) mm		
	Applicator length	Inner Tube: (72.46~72.96) mm Outer Tube: (67.93~68.53) mm	131.0 mm		
	Applicator diameter	Outer Tube: (17.45~18.25) mm	16.7 mm		
Component Materials	Pledget	100% Viscose	100% Viscose	100% organic cotton	Similar
	Overwrap	Non-woven fabric cover: Bi-component 100% Polyethylene/ polyester	Polyethylene & Polyethylene terephthalate	Polyethylene & Polyethylene terephthalate	
	Removal string	67% Polyester/ 33% Viscose	Polyester and cotton	100% organic cotton	
	Applicator	Polyethylene & Polypropylene	Polyethylene & Polypropylene	Polyethylene & Polypropylene	
Additives & Finishing Agents	Anti-wicking agent	Repellan T	Repellan T	Repellan T	Same
	Finishing agent	Fiber finishes	Fiber finishes	Fiber finishes	
Complies with ISO 10993-1		Yes	Yes		Same
Complies with microbiology requirements of FDA guidance for tampons		Yes	Yes		Same

Comparison Item	Subject Device	Predicate Device (K231341)	Comment
Complies with performance testing requirements of FDA guidance for tampons	Yes	Yes	Same
Labeling	Complies with 21 CFR part 801 and FDA guidance for tampons	Complies with 21 CFR part 801 and FDA guidance for tampons	Same

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

PERFORMANCE DATA:

The following performance characteristics were assessed on the SABA® 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
- Tampon integrity
- Chemical residues

BIOCOMPATIBILITY:

Biocompatibility testing was performed on the Saba® tampon in compliance 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'" of Sept. 8, 2023, as follows:

- In vitro cytotoxicity test per ISO 10993-5:2009
- Skin sensitivity test per ISO 10993-10:2021
- Vaginal irritation test per ISO 10993-23:2021
- Acute systemic toxicity test per ISO 10993-11: 2017

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 device and the test results showed 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

CLEANING, DISINFECTION & SHELF-LIFE TESTING

The SABA® Tampons are single use, disposable and non-sterile. The tampons including its applicators cannot be cleaned, disinfected, sterilized or reused by the user.

The SABA® Tampons have been validated to have a 36 month product shelf life when packaged in its retail packaging.

SOFTWARE:

This device does not include any use of software.

ELECTRICAL SAFETY & EMC:

The device does not have any electrical source so no electrical safety or EMC testing are included in this submission.

ANIMAL STUDIES:

No animal studies are included in this submission.

CLINICAL STUDIES:

No clinical studies are included in this submission.

CONCLUSION:

The nonclinical tests completed on the subject device demonstrate the subject device is as safe and effective as the legally marketed device (K231341). Therefore, the subject device is substantially equivalent to the predicate device.