October 7, 2019

ALBAAD fem
c/o Robert Staab
Official Correspondent
Regulatory Technical Associates
30 Neck Road
Old Lyme, CT 06371

Re: K191431
Trade/Device Name: Interlude Rolled Tampons in Plastic Applicator
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: August 30, 2019
Received: September 4, 2019

Dear Robert Staab:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Sharon Andrews
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191431

Device Name
Interlude Rolled Tampons in Plastic Applicator

Indications for Use *(Describe)*
Interlude rolled tampons in plastic applicator are inserted into the vagina and used to absorb 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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510(k) Summary – K191431

1. Submitter Information

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2. Correspondent Information

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3. Date Prepared: October 01, 2019

4. Device Information

Device Name:	Interlude Rolled Tampons in Plastic Applicator
Common Name:	Unscented Menstrual Tampon
Regulation Number:	21 CFR 884.5470
Regulation Name:	Tampon, Menstrual, Unscented
Regulatory Class:	Class II
Product Code:	HEB

5. Predicate Device Information

The predicate device is Interlude and private label Unscented 3-piece compact applicator tampon (K173225). This predicate device has not been subject to a design-related recall.

6. Device Description

Interlude rolled tampons in plastic applicator are menstrual tampons used to absorb menstrual fluid. These tampons will be provided with 3 absorbencies - Regular, Super and Super Plus. These Tampons are rolled and made from organic cotton and polymeric overwrap in which a cotton cord is inserted. The applicator tubes are made of plant-based polyethylene and include a cylindrical barrel with finger grip and a one-piece plunger. The assembled tampon with applicator is wrapped in a printed PE wrapper.

- Regular size absorbency = 6 - 9 grams
- Super-size absorbency= 9 - 12 grams
- Super plus size absorbency = 12 -15 grams

7. Indications for Use

Interlude rolled tampons in plastic applicator are inserted into the vagina and used to absorb menstrual or other vaginal discharge.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

	Subject Device (K191431)		**Predicate Device (K173225)**	
Product Name	Interlude Rolled Tampon in Plastic Applicator		Interlude and private label Unscented 3-piece compact applicator tampon	
Classification Regulation	884.5470		884.5470	
Product Code	HEB		HEB	
Intended Use	Interlude rolled tampons in plastic applicator are inserted into the vagina and used to absorb menstrual or other vaginal discharge.		Interlude and other private label unscented 3-piece compact applicator tampons are inserted into the vagina and used to absorb menstrual or other vaginal discharge.	
Sterile?	No		No	
Design	Compact style applicator with cylindrical barrel with finger grip and one-piece plunger. Digital tampon with round tip and straight grooves.		Compact style applicator with cylindrical barrel with finger grip and two-piece plunger. Digital tampon with round tip and straight grooves.	
Syngyna Absorbency (gram)	Regular	6.0 - 9.0	Regular	6.0 - 9.0
	Super	9.0 - 12.0	Super	9.0 - 12.0
	Super plus	12.0 – 15.0	NA	
Pledget Length (mm)	46±2		46±2	
Pledget Diameter (mm)	11±1, 14±1, 16±1		14±1, 16±1	
Overwrap composition	PE/PES		PE/PES	
Pledget composition	Organic cotton		Viscose rayon	
Withdrawal cord	Organic cotton		Polyester cotton	
Cord length	110-140 mm		110-130 mm	
Applicator	LDPE		LDPE/HDPE barrel; PP pushers	
Primary packaging	Polypropylene		Polypropylene	

The subject and predicate devices have the same intended use – to absorb menstrual or other discharge in the vagina. They have the same design and comparable dimensions and absorbencies. The differences in technological characteristics do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Performance testing

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

- Dimensions
- Absorbency range
- Chemical residues
- Withdrawal cord strength
- Fiber shedding
- Tampon integrity

Biocompatibility Testing

Biocompatibility studies were performed in accordance with the FDA guidance document "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" issued in 2016 and ISO 10993 standards as follows:

- Cytotoxicity (MEM Elution Test) per ISO 10993-5:2009
- Sensitization (Guinea Pig Maximization Test) per ISO 10993-10:2010 (R) 2014
- Irritation (Vaginal Irritation Test) per ISO 10993-10:2010 (R) 2014
- Acute Systemic Toxicity per ISO 10993-11:2006

These tests were performed on the subject tampons and applicators, and the results met the requirements of the ISO standards.

Microbiology Testing

Per the 2005 FDA guidance document mentioned above, microbiology testing was conducted to demonstrate that the subject devices do 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. Conclusions

The subject and predicate devices have the same intended use. Although there are differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate devices.