November 2, 2018

ALBAAD fem
% Robert J. Staab, Ph.D.
Official Correspondent
Regulatory Technical Associates
30 Neck Road
Old Lyme, CT 06371

Re: K181911
Trade/Device Name: Interlude 100% Cotton Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: October 3, 2018
Received: October 4, 2018

Dear Robert J. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K181911

Device Name
Interlude 100% Cotton Tampon

Indications for Use *(Describe)*
Interlude 100% Cotton Tampons are inserted into the vagina and used to absorb menstrual or other 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 – K181911

1. Submitter Information

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2. Correspondent Information

Contact:	Robert J. Staab
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3. Date prepared: October 31, 2018

4. Device Information

Device Name:	Interlude 100% Cotton Tampon
Common Name:	Unscented Menstrual Tampon
Regulation Number:	21 CFR 884.5470
Regulation Name:	Unscented Menstrual Tampon
Regulatory Class:	Class II
Product Code:	HEB (Tampon, Menstrual, Unscented)

5. Predicate Device Information

Tampons (K001641) manufactured by, ROSTAM LTD. This predicate device has not been subject to a design-related recall.

6. Device Description

Interlude 100% Cotton Tampons are menstrual tampons used to absorb menstrual fluid. These tampons are made from cotton absorbing fibers and cotton overwrap to which a cotton cord is sewed with a cotton sewing thread. The applicator tubes are made of cardboard and include a cylindrical barrel and a plunger. The assembled tampon with applicator is wrapped in a printed paper, polyethylene (PE), or polypropylene (PP) wrapper. The subject devices are provided with the following three absorbencies:

Light: <6 grams
Regular: 6-9 grams
Super: 9-12 grams

6. Indications for Use

Interlude 100% Cotton Tampons are inserted into the vagina and used to absorb menstrual or other discharge.

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

Devices	K181911 (subject device)	K001641 (predicate device)
Intended use	Same as the predicate device	The device is inserted into the vagina and used to absorb menstrual or other discharge.
Design (pledget)	Same as the predicate device	A cotton absorbing pledge with overwrap and withdrawal cord
Absorbency	Same as the predicate device	Multiple absorbencies
Material	Cotton	Cotton, polyethylene, polypropylene, and other material(s)
Assembly dimension	• Length: 110-140 mm • Applicator barrel diameter: Light – 11.3-12.7 mm Regular – 13.3-14.7 mm Super – 15.3-16.7 mm	• Length: 115-145 mm • Applicator barrel diameter: N/A
Applicator	Same as the predicate	Cardboard

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 predicate device uses multiple materials, whereas the subject device uses single material. The differences in technological characteristics do not raise different questions of safety or effectiveness.

8. Summary of Non-Clinical Performance Testing

Performance testing

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

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

Microbiology testing

Per the 2005 FDA guidance 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

Biocompatibility testing

Biocompatibility studies were performed in accordance with FDA guidance "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 the ISO 10993 standards, as follows:

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

These tests were performed on the subject tampons, and the results met the requirements of the ISO standards. In addition, biocompatibility data in K001641 and K173225 are leveraged to support the subject applicators.

9. Conclusion

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.