June 15, 2018

ALBAAD fem
℅ Robert Staab
Official Correspondent
Regulatory Technical Associates
30 Neck Road
Old Lyme, Connecticut 06371

Re:   K173225
Trade/Device Name: Interlude and private label Unscented 3-piece compact applicator tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: Class II
Product Code: HEB
Dated: May 14, 2018
Received: May 14, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);
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
Interlude and private label Unscented 3-piece compact applicator tampon

Indications for Use (Describe)
Interlude and private label Unscented 3-piece applicator tampons 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)
- [X] 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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAS Staff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
K173225 510(k) SUMMARY

1.0 Submitter: ALBAAD fem

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Date 510(k) Summary was prepared: 06/14/2018

2.0 Submission Correspondent:

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3.0 Name of the device:

Trade Name: Interlude and private label Unscented 3-piece compact applicator tampon
Device Name: Unscented 3-piece compact applicator tampon
Common Name: Unscented menstrual tampon
Device Class: Class II
Regulation Name: Unscented menstrual tampon
Regulation Number: 21 CFR 884.5470
Product Code: HEB (tampon, menstrual, unscented)

4.0 Predicate Device Information:

The predicate device is K090071, Rostam Fragranced and Unfragranced Compact Applicator Tampons, Rostam Limited

The predicate device has not been subject to a design-related recall
5.0 Description of the Device:

A. Device Description and Dimensions

Interlude and private label Unscented 3-piece compact applicator tampons are menstrual tampons used to absorb menstrual fluid. These tampons are provided in 2 absorbencies, regular and super.

These tampons are made from rayon fibers and polymeric overwrap. The withdrawal cord is made of cotton and polyester. The applicator tubes are made of polyethylene (PE) and include a cylindrical barrel with a finger grip and a two-piece plunger. The assembled tampon with applicator is wrapped in a printed PE wrapper.

B. Physical Properties and Weight

a. Dimensions and Weight

Regular size length = 114.4 mm  
Regular size diameter = 14 mm  
Regular size weight = 2.25 g

Super size length = 114.4 mm  
Super size diameter = 16 mm  
Super size weight = 2.4 g

b. Absorbency

Regular size absorbency = 6 – 9 grams  
Super size absorbency = 9 – 12 grams

C. Device Materials

a. The pledget absorbing fibers are made of rayon. The finishing agent for the rayon fibers is a polyglycol ester and fatty alcohol mixture, Leomin or glycerol.

b. The non-woven over-wrap is a bi-component thermoplastic nonwoven.

c. The withdrawal cord is made from polyester and cotton, and includes an antiwicking agent consisting of a paraffin wax emulsion.

d. The applicator is made from high density polyethylene (HDPE), low density polyethylene (LDPE) and polypropylene.
6.0 Indications for Use

Interlude and private label Unscented 3-piece applicator tampons are inserted into the vagina and used to absorb menstrual or other vaginal discharge.

9.0 Predicate Device Comparison

The table below shows similarities and differences between the predicate device and the subject device.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Predicate Device</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>Rostam Scented and Unscented plastic COMPACT applicator Tampons</td>
<td>Interlude and private label Unscented 3-piece compact applicator tampon</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Rostam Limited</td>
<td>ALBAAD fem</td>
</tr>
<tr>
<td>510(k)</td>
<td>K090071</td>
<td>K173225</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Rostam Fragranced and Unfragranced Compact Applicator Tampons are inserted into the vagina and used to absorb menstrual or other vaginal discharge</td>
<td>Interlude and private label Unscented 3-piece applicator tampons are inserted into the vagina and used to absorb menstrual or other vaginal discharge.</td>
</tr>
<tr>
<td>Device Design</td>
<td>Compact applicator with cylindrical barrel and one-piece plunger. W folded tampon with round mushroom tip</td>
<td>Compact style applicator with cylindrical barrel with finger grip and two-piece plunger. Tampon with round tip and straight grooves.</td>
</tr>
<tr>
<td>Overwrap composition</td>
<td>Polyethylene/Polypropylene Nonwoven</td>
<td>Polyethylene/Polyethylene Terephthalate Nonwoven</td>
</tr>
<tr>
<td>Withdrawal cord composition</td>
<td>Cotton</td>
<td>Polyester and Cotton</td>
</tr>
<tr>
<td>Pledget composition</td>
<td>Viscose Rayon</td>
<td>Viscose Rayon</td>
</tr>
<tr>
<td>Plastic Applicator</td>
<td>Polyethylene</td>
<td>HDPE, LDPE, polypropylene</td>
</tr>
<tr>
<td>Primary Packaging (i.e. wrapper)</td>
<td>Printed Polypropylene</td>
<td>Printed Polyethylene</td>
</tr>
</tbody>
</table>

The Interlude and private label Unscented 3-piece compact applicator tampon is a modification of the Rostam Scented and Unscented plastic COMPACT applicator Tampons. The modifications include material and physical design changes, including differences in the overwrap composition, applicator composition, packaging, and minor dimensional differences in the applicator and pledget.
These differences do not raise different questions of safety and effectiveness. The intended use of the subject and predicate device are identical, to absorb menstrual or other vaginal discharge.

10.0 Summary of Performance Testing:

Biocompatibility

Biocompatibility studies were performed in accordance with the 2016 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”* and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)

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

Performance Characteristics

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*:

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

Microbial Testing

Per the 2005 FDA guidance document *Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) – Guidance for Industry and FDA Staff*, tampon manufacturers should demonstrate that the subject device in its final, finished 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
To assess these parameters, the following tests were performed:

- Zone of inhibition assay assessing the effects of the subject device on the representative microorganisms considered as normal microflora and/or microflora from the infected genitourinary tract
- Evaluation of the tampon’s effect on *Staphylococcus aureus* growth and Toxic Shock Syndrome Toxin-1 production using the tampon-sac/device-sac method

The tests performed met the recommendations of the 2005 FDA guidance document.

11.0 Conclusion:

The results of the performance testing described above demonstrate that the Interlude and private label Unscented 3-piece compact applicator tampon is as safe and effective as the predicate device and supports a determination of substantial equivalence.