August 3, 2023

Tampro, Inc.
% Chris Staab
Vice President of Quality/Regulatory Affairs
Regulatory and Technical Associates
30 Neck Road
Old Lyme, CT 06371

Re: K230419
Trade/Device Name: Sequel Tampon with Plastic applicator
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: June 28, 2023
Received: June 30, 2023

Dear Chris 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,

Monica D. Garcia -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)*
K230419

Device Name
Sequel Tampon with Plastic applicator

Indications for Use *(Describe)*
Sequel tampon with plastic applicator is an unscented tampon provided with a plastic applicator used for easing the placement of the tampon correctly into the vagina. The Sequel tampon is 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
K230419

1.0 Submitter: Tampro Inc.

Name: Greta Meyer
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San Francisco, California 94123
Phone: 215 260 9081
Email: Greta@trysequel.com

Date 510(k) Summary was prepared: July 26, 2023

2.0 Submission Correspondent:

Name: Chris Staab
Address: 30 Neck Road
Old Lyme, CT 06371
Phone: 860 575 5462
Fax: 860 434 5892
Email: RTA1ALI1@aol.com

3.0 Name of the Device

Trade Name: Sequel Tampon with Plastic applicator

Device Name: Sequel Tampon with Plastic applicator

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

5.0 Description of the Device

5.1 Device and Description

The Sequel Tampon with Plastic applicator are menstrual tampons used to absorb menstrual fluid. These Tampons are available in Regular absorbency (6-9 grams).

These Tampons are made from rayon fibers and a polyethylene/polyester overwrap in which a cotton/polyester withdrawal cord is inserted. The applicator is a compact style polyethylene applicator with cylindrical barrel with a plunger. The assembled tampon with applicator is wrapped in a printed polypropylene wrapper. The tampon and applicator are single-use and non-sterile.

5.2 Device Materials

The pledget absorbing fibers are made of rayon. The non-woven over-wrap is a bi-component thermoplastic nonwoven. The withdrawal cord is made from polyester and cotton. Finally, the applicator is made from polyethylene.

The antiwicking agent for the withdrawal cord is a widely used paraffin wax emulsion. The tampon cord contains 2,000 micrograms paraffinic additive/tampon.

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

6.0 Indications for Use

The subject device has the following indications for use:

> "Sequel tampon with plastic applicator is an unscented tampon provided with a plastic applicator used for easing the placement of the tampon correctly into the vagina. The Sequel tampon is inserted into the vagina and used to absorb menstrual or other vaginal discharge."

The predicate device indications for use are:

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

The subject and predicate device have the same intended use, to absorb menstrual or other vaginal discharge. There are no intended use concerns.

7.0 Comparison of Technological Characteristics

The table below is a comparison of the subject and predicate device technological characteristics.

Characteristics	Predicate Device	Subject Device
Device Name	Interlude and Private Label Unscented 3 Piece Compact Applicator Tampon	Sequel Tampon with Plastic applicator
Regulation (Product Code)	21 CFR 884.5470 (HEB)	21 CFR 884.5470 (HEB)
Manufacturer	Albaad fem	Albaad fem
510(k) Number	K173225	K230419
510(k) Owner	Albaad fem	Tampro, Inc
Device Design	Compact style applicator with cylindrical barrel with finger grip and two-piece plunger. Digital tampon with round tip and straight grooves.	Compact style applicator with cylindrical barrel and a plunger. Digital tampon with spiral grooves.
Absorbency	Regular (6-9 grams) Super (9-12 grams)	Regular (6-9 grams)
Pledget Composition	Viscose Rayon	Viscose Rayon
Withdrawal cord composition	Polyester and Cotton	Polyester and Cotton
Overwrap composition	Polyethylene / Polyethylene Terephthalate Nonwoven	Polyethylene / Polyester
Plastic Applicator	High Density Polyethylene, Low Density Polyethylene, Polypropylene	Polyethylene
Primary Packaging	Printed Polyethylene	Printed Polypropylene

The Sequel Tampon with plastic applicator and Interlude and Private Label Unscented3 Piece Compact Applicator Tampon are similar in the pledget composition and components (tampon and applicator). The subject and predicate device differ in the tampon and applicator materials, available absorbencies, as well as the tampon and applicator design. These differences do not raise different questions of safety and effectiveness.

8.0 Summary of Performance Testing

The subject device was assessed for biocompatibility in accordance with the 2020 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 (2018). The tampon was assessed for the following endpoints:

- Cytotoxicity – ISO 10993-5:2009/(R)2014
- Sensitization (Guinea Pig Maximization Test) – ISO 10993-10:2021
- Vaginal Irritation – ISO 10993-23:2021
- Acute Systemic Toxicity – ISO 10993-11:2017

The test results show the tampon is not cytotoxic, non-sensitizing, non-irritating, and does not have acute systemic toxicity. The applicator is the same as the applicator cleared under K020535. Therefore, additional biocompatibility assessments were not completed for the applicator.

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

- Tampon Absorbency via Syngyna testing, per 21 CFR 801.430
- Assessment of Chemical Residues
- String Strength
- Fiber Shedding
- Tampon Integrity
- Microbial Testing to demonstrate the tampon 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

9. Conclusion

The subject and predicate device have the same intended use. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness. The performance data demonstrate that the Sequel Tampon with Plastic applicator is substantially equivalent to the predicate device.