August 13, 2021

Cycle, LLC
% Gabriela McCoole
Quality and Regulatory Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, CA 92129

Re: K211519
Trade/Device Name: Every Cycle™ Reusable Tampon Applicator
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB, HIL
Dated: May 13, 2021
Received: May 17, 2021

Dear Gabriela McCoole:

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 and Part 809); 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
Monica D. Garcia, 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

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)*

K211519

Device Name
Every Cycle™ Reusable Tampon Applicator

Indications for Use *(Describe)*
Every Cycle™ Reusable Tampon Applicator is intended to be used to insert a digital menstrual tampon into the vagina.

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: Cycle, LLC
1927 Washington Avenue
Santa Monica, Ca 90403

Contact Person: Gabriela McCoole
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Date Prepared: August 11, 2021

DEVICE INFORMATION:

Proprietary Name: Every Cycle™ Reusable Tampon Applicator
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Codes: HEB (tampon, menstrual, unscented)
HIL (scented or scented deodorized menstrual tampon)

PRODUCT DESCRIPTION:

The Every Cycle™ Reusable Tampon Applicator is a non-sterile, single user reusable device. It is intended to be sold on its own, without a pre-loaded tampon. The applicator requires the user to load the applicator with a legally-marketed digital/non-applicator menstrual tampon. The use-life of the subject device is two years.

The applicator is comprised of a barrel with a slit, plunger, large (outer) cap, storage compartment, and a small cap.

INDICATIONS FOR USE:

Every Cycle™ Reusable Tampon Applicator is intended to be used to insert a digital menstrual tampon into the vagina.

PREDICATE DEVICE:

The selected predicate device, the re.t.a™ Reusable Tampon Applicator was cleared on August 20, 2018. Thinx Inc, is the owner of the predicate 510(k), K180850.

The predicate device has not been subject to a design-related recall.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Table 1 is a detailed comparison of the Every Cycle ™ Reusable Tampon Applicator with its predicate device.

Table 1 Comparison of the Every Cycle ™ Reusable Tampon Applicator and its predicate

Characteristic	Subject Device	Predicate Device (K180850)	Comparison Evaluation
Product Name	Every Cycle™ Reusable Tampon Applicator	re.t.a™ Reusable Tampon Applicator	N/A
Manufacturer	Cycle LLC	Thinx Inc	N/A
Product Code	HEB (Unscented Menstrual Tampon) and HIL (Scented or Scented Deodorized Menstrual Tampon)	HEB (Unscented Menstrual Tampon) and HIL (Scented or Scented Deodorized Menstrual Tampon)	Same
Intended Use/ Indications for Use	The Every Cycle™ Reusable Tampon applicator is intended to be used to insert a digital menstrual tampon into the vagina.	The re.t.a™ reusable tampon applicator is intended to be used to insert a digital menstrual tampon into the vagina.	Same, other than product name
Design	Barrel with slit, plunger, large (outer) cap, storage compartment, and small cap. Applicator only, does not include tampon.	Sleeve with slit, pusher, and outer cover. Applicator only, does not include tampon.	Different. Subject and predicate device barrel and sleeve design differs. Predicate does not have a storage compartment. This difference is minor and does not raise different issues of safety or effectiveness.
Reuse life	2 years	2 years	Identical.
Tampon Compatibility	Compatible with Super Plus, Super, Regular, and Light absorbency digital tampons. Not for use with Ultra absorbency digital tampons.	Compatible with most digital tampons.	Similar; the subject device is not compatible with the largest size.
Usability	Reusable	Reusable	Identical

PERFORMANCE DATA

The following tests demonstrate that the proposed subject device met the applicable design and performance requirements:

- Use-life testing
- Device weight
- Dimensions
- Functional evaluation, including:
    - Tampon compatibility
    - Ejection force
    - Uncapping force
- Biocompatibility per 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""
    - Cytotoxicity per ISO 10993-5: 2009/(R)2014
    - Vaginal irritation per ISO 10993-10:2010
    - Guinea pig maximization per ISO 10993-10:2010

STERILIZATION & SHELF LIFE TESTING

The cleaning instructions provided for the Every Cycle™ Reusable Tampon Applicator were developed per the recommendations in the 2015 FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." The Every Cycle™ Reusable Tampon Applicator should be washed with unscented soap after every use and sanitized in boiling water after every cycle.

The Every Cycle™ Reusable Tampon Applicator is not provided sterile and is not intended to be sterilized by users. The Every Cycle™ Reusable Tampon Applicator was tested in its expected shipping conditions and verified that the device and its packaging can tolerate the expected shipping stress.

CONCLUSION

The subject and predicate devices have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data provided demonstrate the subject device is substantially equivalent to the predicate device.