June 21, 2024

Menstrual Mates
Cindy Belardo
CEO
16192 Coastal Highway
Lewes, Delaware 19958

Re: K233361
Trade/Device Name: Sunny Cup and Applicator
Regulation Number: 21 CFR 884.5400
Regulation Name: Menstrual Cup
Regulatory Class: II
Product Code: HHE
Dated: May 14, 2024
Received: May 16, 2024

Dear Cindy Belardo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

Reginald K. Avery -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)*
K233361

Device Name
Sunny Cup and Applicator

Indications for Use *(Describe)*
The Sunny Cup and Applicator is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

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.

510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information

Manufacturer:
Menstrual Mates Inc.
16192 Coastal Highway
Lewes, DE 19958

Contact:
Cindy Belardo
Telephone: +1-405-679-7593
E-mail: cindy@sunnyperiod.com

Regulatory Consultant:
Mehdi Kazemzadeh-Narbat, PhD, PMP
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, DC 20001
Phone:202-552-6011
Email: mkazemzadeh@mcra.com

Date Prepared: 11 June 2024

Device Trade Name: Sunny Cup and Applicator

2. Device Information

Common Name: Menstrual Cup

Classification Name: Menstrual Cup

Classification Number: 21 CFR 884.5400

Device Class: II

Product Code: HHE (Cup, Menstrual)

3. Predicate Device Information

Predicate: SckoonCup (K120107)

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

4. Device Description

The Sunny Cup and Applicator is an over the counter (OTC) medical device consisting of a reusable silicone menstrual cup with a lubricious coating and a reusable applicator with a nylon body and a thermoplastic polyurethane (TPU) tip with a lubricious coating. The Sunny Cup is a soft receptacle designed for placement within the vaginal canal to hold up to 25 mL of menstrual fluid and can remain within the body for up to 12 hours. The Sunny Cup is also designed with grip lines and a stem on the distal end to allow for easy location and manipulation of the Sunny Cup during removal.

The Applicator component enables the insertion process for the user and consists of a barrel, a pusher, and a pusher base, functioning similarly to a tampon applicator. For the insertion process, the Sunny Cup is folded and placed in the Applicator barrel. The pusher component is then used to deploy the Cup through the Applicator. The Sunny Cup then unfolds upon deployment to create a seal in the vaginal canal and collect menstrual fluid. After 12 hours, the Sunny Cup is removed manually by squeezing the grip lines to break the seal and pulling the Cup out by the grip lines along the base of the Cup. The Cup component should be cleaned via boiling at the start of each menstrual cycle, and the Cup and Applicator components should be cleaned with warm water and mild, fragrance-free soap between uses. The Sunny Cup and Applicator may be reused by a single patient for up to a year or until discoloration or damage is evident.

5. Indications for Use

The Sunny Cup and Applicator is a receptacle placed in the vagina to collect blood and cellular debris that is exuded from the uterus via the cervix during menstruation.

6. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the Sunny Cup and Applicator are substantially equivalent to the technological characteristics of the predicate device. Both the Sunny Cup and the predicate device are similarly shaped menstrual cups that have the same overall cup length. Additionally, both cups are composed of a soft silicone elastomer material and are supplied non-sterile. Apart from cup insertion, the subject device and the predicate device also have identical principles of operation, including duration of use (i.e., up to 12 hours), reusability, cleaning / reprocessing requirements, and method of cup removal. During insertion, however, the Sunny Cup is manually folded and placed in the Applicator, a component unique to the Sunny device, which is then inserted into the vagina where the Cup is deployed. The predicate device is similarly manually folded but then inserted into the vagina without an applicator. The Sunny Cup and Applicator also have different patient-contacting materials than the predicate device, including a

lubricious coating on the Sunny Cup and Applicator to aid in the insertion process and the nylon and TPU materials of the Applicator. Further, the Sunny Cup diameter and stem length dimensions and volume capacity differ slightly from the predicate device. Comparatively, the Sunny Cup has a slightly larger diameter than Size 2 of the predicate device, and the Sunny Cup volume falls within the volumes listed for Size 1 and Size 2 of the predicate device. These differences in the technological characteristics between the Sunny Cup and Applicator and the predicate device do not raise different questions of safety and effectiveness.

The following table compares the subject device to the predicate device with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Characteristics	Subject Device	Predicate Device	Significant Differences
Device Name	Sunny Cup and Applicator	SCKOONCUP (K120107)	N/A
Regulation Name	Menstrual Cup	Menstrual Cup	Same
Manufacturer	Menstrual Mates Inc.	Sckoon Inc.	N/A
Product Code	HHE	HHE	Same
Regulation Number	21 CFR 884.5400	21 CFR 884.5400	Same
Classification	Class II	Class II	Same
Indications for Use	The Sunny Cup and Applicator is a receptacle placed in the vagina to collect blood and cellular debris that is exuded from the uterus via the cervix during menstruation.	SckoonCup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.	Same
Overall design	Menstrual cup manually folded into reusable applicator which is then used to insert into the vagina	Menstrual cup manually inserted into vagina	Different; reusable applicator for the subject device only
Unscented/Scented	Unscented	Unscented	Same

Dimensions of menstrual cup	70.75 mm (total length from rim to stem of menstrual cup size 1) x 48.85 mm (total diameter of menstrual cup cup size 1)	70 mm (total length from rim to stem of menstrual cup)x 40 mm and 45 mm (total diameter of menstrual cup)	Different
Materials of cup	Silicone elastomer with lubricous coating	Silicone elastomer	Different
Volume of Fluid	Menstrual cup holds 25 mL	Menstrual cup holds 23 mL	Different
Applicator dimensions	Barrel Max Diameter: 26.97 mm Barrel Length: 73.75 mm Barrel Base Diameter: 27.7 mm Pusher Max Diameter: 22.72 mm Pusher Length: 75 mm Pusher Base Diameter: 30.39 mm	N/A	Different
Applicator Materials	Nylon, thermoplastic polyurethane with lubricious coating, and polypropylene	N/A	Different
Duration of use (per use)	12 hours	12 hours	Same
Sterile	No	No	Same
Single-Use	No	No	Same
The subject device has the same indications for use as the predicate device as well as similar technological characteristics. The differences include the use of an applicator, material composition and dimensions; however, the differences do not raise different questions of safety and effectiveness.			

7. Performance Testing - Bench

Bench performance testing verified that the Sunny Cup and Applicator met the pre-specified requirements to demonstrate the Cup and Applicator can withstand anticipated applied forces during cup deployment, and that the Cup met the 25 mL volume capacity

and folding requirements throughout its use-life.

8. Biocompatibility Testing

Biocompatibility studies were performed in accordance with the FDA guidance document "Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process" issued September 2023 as follows:

- Cytotoxicity test per ISO 10993-5:2009 (cup and applicator)
- Sensitization test per ISO 10993-10:2021 (cup and applicator)
- Vaginal irritation test per ISO 10993-23:2021 (cup only)
- Intracutaneous (intradermal) reactivity test per ISO 10993-23:2021 (applicator only)
- Acute systemic toxicity test per ISO 10993-11:2017 (cup only)

All tests were performed on the cup and applicator separately. The results demonstrated that the subject device is non-cytotoxic, nonirritating, non-sensitizing, and non-systemically toxic.

9. Reprocessing and Cleaning Validation:

The Sunny Cup and Applicator is not provided sterile. Reprocessing validation testing demonstrated acceptability of the Cup and Applicator cleaning procedures as included in the Instructions for Use and validated the ability of the Cup and Applicator to withstand repeated reprocessing.

10. Clinical Testing

No clinical study is included in this submission.

11. Conclusion:

In conclusion, the Sunny Cup and Applicator is demonstrated to be as safe and as effective as the SckoonCup. The Sunny Cup and Applicator has the same intended use, principles of operation, and similar technological characteristics as the identified predicate device. The provided performance testing and labeling demonstrate the subject device is as safe and effective as the predicate device. Thus, the Sunny Cup and Applicator is substantially equivalent to the predicate device.