August 18, 2023

Annes Daye, Ltd.
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K223883
Trade/Device Name: Daye Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: July 10, 2023
Received: July 10, 2023

Dear Sheila Hemeon-Heyer:

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,

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)*
K223883

Device Name
Daye Tampon

Indications for Use *(Describe)*
The Daye Tampons are indicated for insertion into the vagina to absorb menstrual 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

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

A. 510(k) Applicant:

Anne's Daye Ltd.
The Biscuit Factory
100 Drummond Road
Bermondsey, London
SE16 4DG, UK

Contact: Valentina Milanova, CEO
Phone: +44 73 66 45 6294
Email: Valentina@yourdaye.com

B. Date Prepared: August 17, 2023

D. Device Name and Classification Information:

Trade Name:	Daye Tampon
Common Name:	Menstrual Tampon
Classification Name:	Tampon, Menstrual, Unscented
Classification Regulation:	21CFR 884.5470
Product Code:	HEB (Tampon, Menstrual, Unscented)
Regulatory Class:	II

E. Predicate Device(s): (K162746) W long plastic applicator Tampons by Ontex BVBA

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

F. Device Description: The Daye Tampons are unscented menstrual tampons consisting of an absorbent cotton pledget and a plastic (polyethylene) full-size applicator. The tampon pledget is made entirely of organic cotton, is fashioned with a 'W' wadding design and protective sleeve/overwrap. A withdrawal cord, made from mercerised organic cotton, is attached to the pledget. The Daye Tampons are available in regular (6-9 grams) and super (9-12 grams) absorbencies. The Daye Tampons and applicator are gamma irradiated in the final packaging. The Daye Tampons and applicators are repackaged together.

G. Indications for Use Statement: The Daye Tampons are indicated for insertion into the vagina to absorb menstrual discharge.

H. Comparison with Predicate Device: The following table compares the Daye Tampons to the predicate device (Ontex W long plastic applicator Tampons) with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

Parameter	Proposed Device K223883		Predicate Device K162746		Comparison
Device Trade Name	Daye Tampon		W Long Plastic Applicator Tampons		N/A
Device Manufacturer	Anne's Daye		Ontex BVBA		N/A
Classification regulation	21CFR 884.5470		21CFR 884.5470		Same
Product Code	HEB		HEB		Same
Indications for Use Statement	The Daye Tampons are indicated for insertion into the vagina to absorb menstrual discharge.		The W long Tampons are inserted into the vagina to absorb menstrual discharge.		Same
Intended use population	Menstruating females		Menstruating females		Same
Rx or OTC	OTC		OTC		Same
Product design	W wadding with a full size (long) applicator		W wadding with a full size (long) applicator		Same
Materials:					
Tampon and withdrawal cord	100% cotton pledget and withdrawal cord		100% cotton pledget and withdrawal cord		Same
Applicator	Plastic (polyethylene)		Plastic (polyethylene)		Same
Additives and finishing agents	MICROCOLOR-Pearl white (coloring component, 2%) SICOBATCH AD PE GL Natural (lubricant)		MICROCOLOR-Pearl white (coloring component, 2%) SICOBATCH AD PE GL Natural (lubricant)		Same
Tampon Dimensions:	Regular	Super	Regular	Super	
Length (mm)	45 ± 5	45 ± 5	45 ± 5	45 ± 5	Same
Diameter (mm)	13.5 ± 0.2	15.5 ± 0.2	13.5 ± 0.2	15.5 ± 0.2	Same
Weight (g)	1.9 – 2.3	3.0 – 3.4	1.9 – 2.3	3.0 – 3.4	Same
Absorbency (g)	6-9	9-12	6-9	9-12	Same
Applicator Dimensions: Length (mm)	77 (closed)		77 (closed)		Same

Parameter	Proposed Device K223883		Predicate Device K162746		Comparison
Diameter (mm)	115-135 (extended)		115-135 (extended)		Same
	14.9	16.9	14.9	16.9	Same
Withdrawal cord length (mm)	120 ± 15		120 ± 15		Same
Irradiated	Yes, Gamma, 10 kGy (not labelled sterile)		No		Different
Single use	Yes		Yes		Same
Tampon wrapper	Cellulose-based; Intended to dissolve in water		Not provided		Different
Biocompatibility complies with ISO 10993-1	Yes		Yes		Same
Microbiology complies with FDA Guidance for Tampons	Yes		Yes		Same

I. Discussion of Differences

Daye Tampons are the same as the Ontex Tampons that were cleared under K162746. The differences are:

1. The subject device Daye tampons and applicator are irradiated using gamma radiation after packaging in the wrapper. The predicate device is not irradiated prior to use.

2. The Daye Tampon wrapper is designed to dissolve in water.

These differences do not raise different questions of safety and effectiveness.

J. Summary of Data Submitted to Support Substantial Equivalence

As outlined in the 2005 FDA guidance document, Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s), the subject device was assessed for performance characteristics, toxicology (biocompatibility), and microbiology, summarized below.

Biocompatibility:

Biocompatibility evaluation was performed according to the following requirements of the 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"" issued September 2020 for the tampon and applicator as follows:

- Cytotoxicity testing per ISO 10993-5:2009
- Local Lymph Node Assay Sensitization testing per ISO 10993-10:2010
- Vaginal Irritation testing per ISO 10993-10:2010

The biocompatibility testing demonstrated the tampon is non-cytotoxic, non-sensitizing, non-irritating, and not acutely systemically toxic. The biocompatibility testing demonstrated the applicator is non-cytotoxic, non-sensitizing, and non-irritating.

Physical and Performance Characteristics

Unaged Daye tampons that were gamma irradiated using a dose of 10 kGy were subjected to the following tests:

- Dimensional analysis, including
  - Applicator Overall Length
  - Applicator Plunger Length
  - Applicator Barrel Length
  - Outer Diameter at top of applicator barrel
  - Outer diameter at base of barrel of applicator
  - Tampon overall length
  - Tampon Diameter
- Absorbency testing using the Syngyna method (per 21CFR 801.430)
- Withdrawal cord strength testing
- Fiber loss testing
- Tampon integrity

Chemical Residues testing

The sponsor leveraged chemical residue testing completed on the predicate device to support chemical residue testing of the subject device. Given the device is identical to the predicate device except for gamma irradiation and repackaging, chemical residue testing can be leveraged from the predicate device to support the chemical residues of the subject device.

The results of these tests demonstrated that:

- Gamma radiation had no effect on any of the measured product dimensions.
- The absorbency for both the regular and super Daye Tampons remained within the required absorbency ranges of 6-9 grams for regular absorbency tampons and 9-12 grams for super absorbency tampons, per 21CFR 801.430.

- Withdrawal cord strength of the irradiated tampons is similar to non-irradiated tampons
- Gamma radiation did not increase fiber shedding as compared to non-radiated tampons

The conclusion of this testing is that gamma radiation of the Daye regular and super tampons did not impact the tampon's physical and performance characteristics.

Microbiology Characteristics

The subject device leveraged microbiology testing completed on the predicate device. Because the subject device is identical to the predicate device except for gamma irradiation and repackaging, microbiology testing for the tampon can be leveraged from the predicate device. The microbiology testing demonstrated that the subject device tampon does not:

- enhance the growth of *Staphylococcus aureus*,
- increase the poduction of Toxic Shock Syndrome Toxin-1 (TSST-1), and
- alter the growth of normal vaginal microflora.

Wrapper Testing

The Daye tampon wrapper is designed to dissolve in water. Storage testing demonstrated that the wrapper is not adversely affected when exposed to 90% humidity for 30 minutes, but completely dissolves after approximately 15 seconds when placed in water.

K. Conclusion

The non-clinical data described above demonstrate that the Daye Tampons are as safe and effective as the predicate device and support a determination of substantial equivalence.