January 6, 2023

Kimberly-Clark Corporation
% Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
25 Independence Blvd
Warren, NJ 07059

Re: K223749
Trade/Device Name: U by Kotex® Click® Unscented Menstrual Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: December 11, 2022
Received: December 14, 2022

Dear Dave Yungvirt:

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,

Jason Roberts -S

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)*
K223749

Device Name
U by Kotex® Click® Unscented Menstrual Tampon

Indications for Use *(Describe)*
U by Kotex® Click® Unscented Menstrual Tampon is an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid.

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

1. Submitter Information

Applicant: Kimberly-Clark Corporation
Address: 2100 Winchester Road
Neenah, WI 54956

2. Correspondent Information

Contact: Jeremy D. Paulsen
Sr. Regulatory Affairs Product Manager
Address: 2100 Winchester Road
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Phone: +1 (920) 721-2552
Email: Jeremy.paulsen@kcc.com

3. Date Prepared:

January 3, 2023

4. Device Information

Trade Name: U by Kotex® Click® Unscented Menstrual Tampon
Common Name: Tampon, Menstrual, Unscented
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: Class II
Product Code: HEB
Classification Panel: OBGYN, Obstetrics/Gynecology

5. Predicate Device Information

Kimberly-Clark's U by Kotex® Click® Unscented Menstrual Tampon (K172118). This device has not been subject to a design-related recall.

6. Device Description

The U by Kotex® Click® Unscented Menstrual Tampon is a conventional unscented menstrual tampon consisting of an absorbent pledget and a telescoping three-piece plastic applicator. The device will be manufactured in Regular, Super, and Super Plus absorbencies. The absorbent pledget consists of an absorbent core of radially wound rayon ribbon compressed into a grooved cylinder with a rounded, bullet-like tip, a non-woven overwrap cover, and a rayon-polyester blend withdrawal string.

The three-piece applicator consists of an outer insertion tube (barrel) with a textured grip and formed with a closed, rounded tip in a petal-like design, a clear middle telescopic tube (telescope), and an elongated insertion tube (plunger). Each tampon is individually sealed in a plastic film primary wrapper and then packaged in sealed multi-unit containers for retail sale.

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7. Indications for Use

The Kimberly-Clark U by Kotex® Click® Unscented Menstrual Tampon is an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The subject device and the predicate device have the same functional design, intended use and indications for use. In addition, both have the same material composition and are produced using the same manufacturing processes.

Summary of technological characteristics compared to the predicate device:

The device is the same as the predicate device with respect to materials and functional design.

The difference between the subject and predicate device is the placement distance of the withdrawal string from the edge of the absorbent pledget ribbon prior to rolling and compressing. There are minor differences in the applicator's barrel diameter and weight of the regular absorbent pledget compared to that of the predicate device. The subject device applicator is the same as the predicate device applicator in all other respects. There will also be minor changes to the packaging artwork and labeling.

Table 05-01 below compares the U by Kotex® Click® Unscented Menstrual Tampon to the predicate device with respect to indications for use, principles of operation, technological characteristics, and materials.

Table 05-01: Summary of technological characteristics compared to the predicate device:

Characteristic Description	Subject Device	Predicate Device
Trade Name	Same	U by Kotex® Click® Unscented Menstrual Tampon
Product Code	Same	HEB
510(k) Number	TBD	K172118
Common Name	Same	Tampon, Menstrual, Unscented
Classification Name	Same	Tampon, Menstrual, Unscented (21 CFR 884.5470, Product Code HEB)
Indications for use	Same	The Kimberly-Clark U by Kotex® Click® Unscented Menstrual Tampon is an

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Characteristic Description	Subject Device	Predicate Device
		unscented menstrual tampon inserted into the vagina to absorb menstrual fluid.
Patient Population	Same	Menstruating Women
Absorbencies	Same	Regular (6-9g), Super (9-12g), Super Plus (12-15g)
Sterile	Same	No
Single Use	Same	Yes
Description of the device:	Same	Conventional unscented menstrual tampon consisting of an absorbent pledget and a plastic applicator. The absorbent pledget consists of a ribbon of rayon fibers. A rayon -polyester blend withdrawal string is placed on the ribbon and the ribbon is radially wound, then compressed into a traditional eight groove bullet-shaped pledget, overwrapped with a non-woven cover material. The absorbent pledget is inserted into a three-piece plastic applicator consisting of an inner tube (plunger), a clear middle telescopic tube (telescope), and an outer insertion tube (barrel) formed with a closed, rounded tip. Each tampon (absorbent pledget with applicator) is wrapped in an individual plastic film wrapper, and packaged in a sealed multi-unit container for retail sale.
Withdrawal String	**Similar**	String target location:

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Characteristic Description	Subject Device	Predicate Device
Location from the edge of the rayon ribbon	Subject and predicate devices differ with regards to where the withdrawal string is looped around rayon ribbon. This difference does not raise new concerns of safety or efficacy as supported by the performance data. String target location: 150mm	80mm
Applicator Barrel Diameter for Super	12.9mm inner, and 14.16 mm outer diameter	14.20 mm inner, and 15.60 mm outer diameter
Absorbent Pledget: Composition & Weight: Regular	1.53 g	1.48 g
Complies with ISO 10993 series	Same	Yes
Complies with pre-clinical microbiology requirements of FDA Guidance for Tampons*	Same	Yes

*2005 FDA guidance document "Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) – Guidance for Industry and Staff"

9. Overview of Non-Clinical Performance Data

Safety Assessment:

No clinical tests were performed as part of this device modification.

In addition to verifying performance and characteristics, the subject 510(k) device has been assessed for safety according to ISO 10993-1 (2018) and the FDA guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1:

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Evaluation and testing within a risk management process" (2020) and US FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.” Biocompatibility of the subject device is inclusive of the absorbent pledget (includes absorbent core, overwrap cover, and withdrawal string) and three-piece plastic applicator consisting of an inner tube (plunger), a clear middle telescopic tube (telescope), and an outer insertion tube (barrel). Table 05-02 below provides a brief description of the biological endpoints assessed by recognized standards.

Table 05-02: Preclinical Toxicology (Biocompatibility) Tests

Preclinical Tests	Standard	Performance
Genotoxicity Test (MLA)	ISO 10993-3 (2014)	Non-Genotoxic
Genotoxicity Test (AMES)	ISO 10993-3 (2014)	Non-Genotoxic
Genotoxicity Test (Mouse Micronucleus)	ISO 10993-3 (2014)	Non-Genotoxic
Cytotoxicity Test	ISO 10993-5 (2009)	Non-cytotoxic
Mucosal Irritation Test	ISO 10993-23 (2021)	Non-irritating
Mucosal Sensitization Test	ISO 10993-10 (2021)	Non-sensitizing
Acute Systemic Toxicity Test	ISO 10993-11 (2017)	Not Systemically Toxic

The finished subject device, U by Kotex® Click® Unscented Menstrual Tampon, is identical in composition, manufacturing processes, toxicologic profile, and performance to the commercially available predicate. As there are no new or different risks identified, there is no change to the strategy for safety, biocompatibility assessment, or pre-clinical microbiological risk, necessitating additional testing.

Performance Characteristics

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”

Absorbency range
Chemical residues
Withdrawal string strength
Fiber Shedding
Wet and Dry Tampon Integrity
Expulsion Force

10. Conclusion/Statement of Substantial Equivalence

The subject and predicate devices have the same intended use and fundamental technological characteristics. The difference in technological characteristics between the subject and predicate devices does not raise new questions of safety or effectiveness. The performance data demonstrate that the U by Kotex® Click® Unscented Menstrual Tampon is substantially equivalent to the predicate device.