October 11, 2017

Kimberly-Clark Corporation
Lori J. Barr
Kimberly-Clark Corp.
2001 Marathon Ave.
Neenah, WI 54956

Re: K172118
Trade/Device Name: U by Kotex® Click® Unscented Menstrual Tampons
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: July 10, 2017
Received: July 13, 2017

Dear Lori J. Barr:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Sincerely,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Kimberly-Clark Corporation

510(k) Summary
(K172118)

I. Submitter

Submitter/Address:	Kimberly-Clark Corporation 2100 Winchester Road Neenah, WI 54956
Contact Person:	Lori J. Barr
Phone:	920-721-4570
Fax:	920.380.6467
Email:	lori.barr@kcc.com

II. Date Prepared:

October 10, 2017

III. General Information

Device Name:	U by Kotex® Click® Unscented Menstrual Tampons
Common Name:	Unscented Menstrual Tampon
Classification Name:	Unscented Menstrual Tampon (21 CFR 884.5470)
Product Code:	HEB (tampon, menstrual, unscented)
Regulatory Class:	II

IV. Predicate Device:

U by Kotex® Click® Unscented Menstrual Tampons (K113036) manufactured by Kimberly-Clark Corporation. This predicate device has not been subject to any design related recalls.

V. Description of the Device:

The subject devices are conventional unscented menstrual tampons consisting of an absorbent pledget, an overwrap, a withdrawal string, 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 tampon component 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 component with applicator is wrapped in an individual plastic film wrapper, and packaged in a sealed multi-unit container for retail sale. Tampons are available in Regular, Super and Super Plus absorbencies in various counts.

VI. Indications for Use

The U by Kotex® Click® Unscented Menstrual Tampons are inserted into the vagina to absorb menstrual fluid.

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

Criteria	K172118 (subject device)	K113036 (predicate device)
Indications for Use	Same as predicate	Kimberly-Clark U by Kotex Click is an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid.
Design - absorbent pledget	Same as predicate	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 pledget provides three absorbencies: regular, super, and super plus.
Design - Applicator	Same as predicate	The 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.
Material	The non-woven polyester/polyethylene covering the pledget used in the subject devices are from different suppliers. There are no other changes in materials used in the subject and predicate devices.	
The subject and predicate devices have the same indication – an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid. The subject and predicate devices have the same design. The non-woven polyester/polyethylene covering the pledget used in the subject devices are from different suppliers. This difference in technological characteristics does not raise different questions for safety and effectiveness.		

VIII. Summary of Non-Clinical Performance Testing:

The following studies have been performed to support substantial equivalence to the predicate device:

- Biocompatibility testing in accordance with the ISO 10993-1:2009. The testing demonstrated that the pledget is non-cytotoxic, non-sensitizing, non-irritating, and non-toxic.
    * Cytotoxicity testing per 10993-5:2009
    * Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
    * Vaginal Irritation testing per ISO 10993-10:2010
    * Acute Systemic Toxicity testing per ISO 10993-11:2006
- Performance testing in accordance with the FDA Guidance, “Menstrual Tampons and Pads: Information for Premarket Notification Submissions” issued July 27, 2005. The testing confirmed that the design output meets the design inputs and specifications for the device. The testing criteria are as follows:
    * Syngyna (absorbency range) – The subject tampons met the requirements of 21 CFR §801.430(f)(2) for each absorbency level.

* Chemical residues – There were no detectable 2,3,7,8- tetrachlorodibenzo-p-dioxin (TCDD); 2,3,7,8-tetrachlorofuran dioxin (TCDF); or any pesticide and herbicide residues
* Mechanical performance – The subject tampons met the following design specifications:
    - String strength: ≥ 10 lb force
    - Fiber shedding: ≤2 mg/tampon
    - Tampon integrity: ≥20 daN dry and ≥15 daN wet
* Microbiology testing – The subject tampons passed the following tests:
    - Bioburden: Total Aerobic Microbial Count (TAMC) ≤200 cfu/g and Total Yeast/Mold Count (TYMC) ≤20 cfu/g per USP <61>; Absence of pathogenic organisms (S. *aureus*; E. *coli*; P. *aeruginosa*; *Salmonella* species; C. *albicans*; and C. *sakazakii*) per USP <62>
    - Vaginal microflora: The subject tampons did not alter growth of normal vaginal microflora, increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1), or enhance the growth of S. *aureus*.

XI. Conclusion:

The subject and predicate devices have the same intended use. There is a difference in the supplier for the material used in the subject device. However, this difference in technological characteristics does not raise different questions of safety or effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.