December 20, 2019

Ontex BVBA
℅ Rachel Paul
Senior Consultant, QA&RA
Emergo Europe Consulting
Prinsessegracht 20
The Hague, NL 2514AP

Re: K191666
Trade/Device Name: Unscented W long plastic and cardboard applicator Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: Class II
Product Code: HEB
Dated: November 15, 2019
Received: November 19, 2019

Dear Rachel Paul:

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,

For
Monica D. Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191666

Device Name
Unscented W long plastic and cardboard applicator Tampons

Indications for Use *(Describe)*
The Unscented W long plastic and cardboard applicator Tampons are inserted into the vagina to absorb menstrual or other vaginal 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Unscented W long plastic and cardboard applicator Tampons

K191666

1. Submission Sponsor

Ontex BVBA

5 Genthof

Buggenhout Oost-Vlaanderen

9255

Belgium

Phone number: +32 9 376 77 06

Contact: Henri Lesage

Title: Group R&D Manager Strategic Projects & Tampons

2. Submission Correspondent

Emergo Europe Consulting

Prinsessegracht 20

The Hague

2514AP

The Netherlands

Cell Phone: 00 33 6 89 83 16 09

Office Phone: +31 (0) 70 345 8570/Direct: +31 (0) 70 850 8249

Contact: Rachel Paul, Senior Consultant, QA&RA

Email: LST.AUS.ProjectManagement@ul.com

3. Date Prepared

19 December 2019

4. Device Identification

Device Trade Name: Unscented W long plastic and cardboard applicator Tampons

Device Common Name: Unscented menstrual tampons

Regulatory Class: Class II

Regulation Number: 21 CFR 884.5470

Regulation Name: Unscented menstrual tampon

Product Code: HEB (tampon, menstrual, unscented)

5. Legally Marketed Predicate Device

K122603, Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons (Ontex BVBA)

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

6. Device Description

The Unscented W long plastic and cardboard applicator Tampons are unscented menstrual tampons consisting of an absorbent pledget and an applicator. The pledget is made of 100% viscose with polymeric overwrap. The applicator is a full size applicator provided in polyethylene or cardboard. The absorbent pledget has a W wadding design and is available in light, regular, super and super plus absorbencies. For additional technical information, please see Table 1 below.

7. Indication for Use Statement

The Unscented W long plastic and cardboard applicator Tampons are inserted into the vagina to absorb menstrual or other vaginal discharge.

8. Substantial Equivalence Discussion

The following table compares the Unscented W long plastic and cardboard applicator Tampons (subject device) to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

Table 1 – Comparison of Characteristics

Manufacturer	**Ontex BVBA**	**Ontex BVBA**	**Device Comparison**
Trade Name	**W long plastic and cardboard applicator Tampons (subject device)**	**Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons (predicate device)**	
510(k) Number	K191666	K122603	Same

Manufacturer	Ontex BVBA	Ontex BVBA	Device Comparison
Trade Name	**W long plastic and cardboard applicator Tampons (subject device)**	**Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons (predicate device)**	
Product Code	HEB	HEB	Same
Regulation Number	884.5470	884.5470	Same
Regulation Name	Unscented menstrual tampons	Unscented menstrual tampons	Same
Indications for use	The Unscented W long plastic and cardboard applicator Tampons are inserted into the vagina to absorb menstrual or other vaginal discharge.	The Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons, available in light, regular, super, and super plus absorbency are inserted into the vagina and used to absorb menstrual or other vaginal discharge.	Similar
Target Population	Women	Women	Same
Anatomical site	Vagina	Vagina	Same
Overall design	Unscented	Unscented	Same
	W wadding tampons	W wadding tampons	Same
	With applicator	With and without applicator (digital)	Different. The subject device does not contain a digital tampon option. However, both the subject and predicate device utilize an applicator for tampon deployment.
	Long (full size) applicator	Long (full) size applicator	Same
Absorbencies	light (< 6g), regular (6-9g), super (9-12g) and super plus (12-15g)	light (< 6g), regular (6-9g), super (9-12g) and super plus (12-15g)	Same

Manufacturer	Ontex BVBA	Ontex BVBA	Device Comparison
Trade Name	**W long plastic and cardboard applicator Tampons (subject device)**	**Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons (predicate device)**	
Sterile	No	No	Same
Single use	Yes	Yes	Same
Materials	Pledget in 100% TCF viscose	Pledget in a mix of TCF/ECF viscose	Similar. The subject device utilizes a different pledget material.
	New glue for cardboard applicator	Cardboard glue	Similar. The subject device utilizes a different glue in the cardboard applicator.
Dimensions	Tampon Length: 45-50 mm Diameter: 9.8 – 15.5 mm Weight: 1.2 – 4.05 Plastic Applicator Length: 115 - 135 mm Diameter: 12.9 – 16.9 mm Cardboard Applicator Length: 115 - 125 mm Diameter: 12.0 – 16.0 mm	Tampon Length: 45 mm Diameter: 10.6 – 15.5 mm Weight: 1.0 – 3.8 g Plastic Applicator Length: 125mm (74mm for compact applicator only) Diameter: 13.5 – 16.0 mm Cardboard Applicator Length: 120 mm Diameter: 12.0 – 16.0 mm	Different. The subject device has slightly different dimensions and weight.
Complies with ISO 10993-1	Yes	Yes	Same
Complies with microbiology requirements of FDA Guidance for Tampons	Yes	Yes	Same

The subject and predicate device have similar indications for use and have the same intended use. The technological characteristics of the subject device are different. The subject device contains different materials and different dimensions and weight. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions.

9. Non-Clinical Performance Data

Biocompatibility

Biocompatibility studies were performed in accordance with the 2016 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" and ISO 10993-1:2009 as follows:

- ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
- ISO 10993-11:2006, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity (tampon only)

All tests were performed on the tampon and applicator separately. The results of this testing demonstrated that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Performance Characteristics

The following performance characteristics were assessed in accordance with the 2005 FDA guidance document Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) – Guidance for Industry and FDA Staff:

- Dimensional information
- Absorbency range (Syngina testing per 21 CFR 801.430(f)(2))
- Chemical residues
- Withdrawal cord strength
- Fiber shedding
- Tampon integrity
- Expulsion force
- Cardboard applicator dissolving time

Microbial Testing

Per the 2005 FDA guidance document Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) – Guidance for Industry and FDA Staff, tampon manufacturers should demonstrate that the subject device in its final, finished form does not:

- enhance the growth of Staphylococcus aureus

- increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1)
- alter the growth of normal vaginal microflora

The testing performed met the recommendations of the 2005 FDA guidance document.

10. Statement of Substantial Equivalence

The results of the performance testing described above demonstrate that the Unscented W long plastic and cardboard applicator Tampons are as safe and effective as the predicate device and supports a determination of substantial equivalence.