DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 7, 2017

Ontex BVBA
% Rachel Paul
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The Netherlands

Re: K162746
Trade/Device Name: W long plastic applicator Tampons
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: February 2, 2017
Received: February 3, 2017

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. 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 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 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,

Charles Viviano -S

For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162746

Device Name
W long plastic applicator Tampons

Indications for Use *(Describe)*
The W long plastic applicator Tampons are inserted 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.

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510(k) Summary

W long plastic applicator Tampons

K162746

1. Submission Sponsor

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3. Date Prepared

2 March 2017

4. Device Identification

Trade/Proprietary Name: W long plastic applicator Tampons

Common/Usual Name: Unscented menstrual tampons

Regulation Number: 21 CFR 884.5470 (Unscented menstrual tampon)

Product Code: HEB (Tampon, Menstrual, Unscented)

Device Class: Class II

Classification Panel: Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

K090819, Ontex Tampon (Unscented)

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

6. Device Description

The W long plastic applicator Tampons are conventional unscented menstrual tampons consisting of an absorbent pledget and an applicator. The pledget is made of organic cotton. The applicator is in polyethylene and of full size (long). The pledget has a W wadding design. The Tampons are available in regular and super absorbencies. The device specifications are listed in the table below.

Component		Regular	Super
Tampon	Length (mm)	45 ± 5	45 ± 5
	Diameter (mm)	13.5 ± 0.2	15.5 ± 0.2
	Weight (g)	1.9-2.3	3.0-3.4
	Absorbency (g)	6-9	9-12
Applicator	Length (mm)	77.0 (closed) 115-135 (extended)	
	Diameter (mm)	14.9	16.9
Withdrawal Cord	Length (mm)	120 ± 15	

7. Indication for Use Statement

The W long plastic applicator Tampons are inserted into the vagina to absorb menstrual discharge.

8. Substantial Equivalence Discussion

The following table compares the W long plastic applicator Tampons to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The different technological characteristics of the subject device do not raise any different questions of safety or effectiveness compared to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Ontex BVBA**	**Ontex BVBA**	**Significant Differences**
Trade Name	**W long plastic applicator Tampons**	**Ontex Tampons (Unscented)**	
510(k) Number	K162746	K090819	NA
Product Code	HEB	HEB	Same
Regulation Number	884.5470	884.5470	Same
Regulation Name	Unscented menstrual tampons	Unscented menstrual tampons	Same
Indications for Use	Inserted into the vagina to absorb menstrual discharge	Inserted into the vagina to absorb menstrual discharge	Same
Targeted population	Women	Women	Same
Anatomical site	Vagina	Vagina	Same
Where used	Home and can be transported during normal activities of women	Home and can be transported during normal activities of women	Same
Overall design	W wadding With an applicator Full size (long) applicator	W wadding Digital (without applicator) and with applicator Full size (long) applicator	Partially the same; predicate is available without an applicator
Absorbencies (sizes)	Regular and super	Regular and super	Same
Sterile	No	No	Same
Single-Use	Yes	Yes	Same
Materials	Applicator in Polyethylene and all the others parts in 100%	Applicator in cardboard and all the others parts in	Partially the same; applicator is not from

Manufacturer	**Ontex BVBA**	**Ontex BVBA**	**Significant Differences**
Trade Name	**W long plastic applicator Tampons**	**Ontex Tampons (Unscented)**	
	organic cotton	100% organic cotton	the same material
Complies with ISO 10993-1	Yes	Yes	Same
Complies with microbiology requirements of FDA Guidance for Tampons	Yes	Yes	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of W long plastic applicator Tampons that are subject to this 510(k) submission and in showing substantial equivalence to the predicate device, Ontex BVBA completed a number of non-clinical performance tests. The W long plastic applicator Tampons meet all the requirements for overall design, functionality, biocompatibility, and microbiology results confirming that the design output meets the design inputs and specifications for the device.

The W long plastic applicator Tampons passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Dimensional Testing – the dimensions met the final device specifications
- Syngyna testing, expulsion force of the applicator, string strength and fiber shedding per internal requirements – results meet specifications
- Biocompatibility testing per ISO 10993-1:2009/(R)2013 – the tampons and applicator tested are found as non-cytotoxic, non-irritating, non-sensitizing, and non-acutely toxic.
- Microbiology testing for growth of *Staphylococcus aureus*, production of Toxic Shock Syndrome Toxin-1, growth of the normal vaginal microbial species per FDA Guidance on menstrual tampons - the test tampon does not enhance the growth of *Staphylococcus aureus*. It does not increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1). It had no effect on culture pH. The test tampon does not alter the growth of normal vaginal microflora.
- Microbiology batch testing per European Pharmacopeia 2.6.12 and 2.6.13 – the specifications are met

- Pesticides and dioxins testing – no pesticides and dioxins are found from the polyethylene applicator or from the organic cotton.

10. Statement of Substantial Equivalence

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