510(k) Summary

for

ONTEX
ROLL WADDING PLASTIC APPLICATOR COMPACT SIZE UNSCENTED TAMPONS

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3. Date Prepared

16th August 2013

4. Device Identification

Trade/Proprietary Name:	ONTEX ROLL WADDING PLASTIC APPLICATOR COMPACT SIZE UNSCENTED TAMPONS
Common/Usual Name:	UNSCENTED MENSTRUAL TAMPONS
Classification Name:	UNSCENTED MENSTRUAL TAMPON
Classification Regulation:	21 CFR 884.5470
Product Code:	HEB
Device Class:	Class II
Classification Panel:	OBGYN, Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

Ontex Digital and Plastic/Cardboard Applicator Unscented Tampons	K122603

6. Device Description

The Roll wadding plastic Applicator Compact size Unscented Tampon is a menstrual tampon.

These tampons are unscented tampons it means without any perfume.

These tampons are made from viscose material and polymeric overwrap. The withdrawal cord is made from polyester and cotton.

These tampons have an applicator. The applicator is made from plastic (polyethylene). The applicator is in a compact size meaning that the inner tube and the outer tube are slided into each other telescopically so the inner tube needs to be retracted before usage.

These tampons have a Roll wadding form. In a roll tampon, the fleece band is folded and then rolled (like a Swiss roll) before being radially pressed.

The Roll wadding plastic Applicator Compact size Unscented Tampon is available in 3 absorbencies: regular, super, and super plus absorbency (regular (6-9g), super (9-12g), and super plus (12-15g)).

Tampon Type	Applicator material	Applicator Size	Absorbencies
Roll wadding	Plastic	Compact	6-9g, 9-12g, 12-15g

The materials used in these tampons are exactly identical to the materials used to manufacture the predicate devices tampons.

7. Indication for Use Statement

The Roll wadding plastic Applicator Compact size Unscented Tampons are inserted into the vagina to absorb menstrual discharge.

8. Substantial Equivalence Discussion

The following table compares the ROLL WADDING PLASTIC APPLICATOR COMPACT SIZE, UNSCENTED TAMPONS to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A –General Comparison of Characteristics

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	ROLL WADDING PLASTIC APPLICATOR COMPACT SIZE UNSCENTED TAMPONS	DIGITAL AND PLASTIC/CARDBOARD UNSCENTED APPLICATOR TAMPONS (K122603)	Roll wadding design combined with a compact size applicator
510(k) Number	Not yet defined	K122603	
Product Code	HEB	HEB	same
Regulation Number	21 CFR PART 884.5470	21 CFR PART 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
Material	Absorbent pledget in viscose, polymeric overwrap, cotton polyester cord. Plastic applicators in polyethylene.	Absorbent pledget in viscose, polymeric overwrap, cotton polyester cord. Plastic applicators in polyethylene . Cardboard applicators in paper.	same
Tampon Type and Applicator (material and size)	Roll wadding tampon type with a plastic applicator in compact size	Roll wadding tampon digital (without applicator) W wadding tampon type with a plastic applicator in full size (long) and in compact size	Different, roll wadding form combined to compact applicator size
Absorbencies	6-9g, 9-12g, 12-15g	<6g, 6-9g, 9-12g, 12-15g	Different no light absorbency for roll wadding plastic applicator compact size Tampons
Sterile	no	no	same
Single-Use	yes	yes	same
Complies with ISO 10993-1	yes	yes	same

9. Non-Clinical Performance Data

As the intended use (same type and duration of user contact), raw materials and manufacturing process are the same, it was not necessary to test again the biocompatibility (irritation, sensitization, cytotoxicity and acute systemic toxicity) and microbiology (growth of *S.aureus*, TSST-1, normal vaginal microflora) of the Roll wadding plastic Applicator Compact Size Unscented Tampons. The results of tests performed on the predicate are still applicable. The modifications do not adversely alter the safety profile of the tampons.

The Roll wadding plastic Applicator Compact size Unscented Tampons are recognized to be non-cytotoxic, non-irritant, with no terminal or gross observations in the reproductive tracts of any of the animals, with no exhibiting toxic signs, and with a negligible dermal response. They did not present a potential for dermal irritation or allergic contact sensitization.

The Roll wadding plastic Applicator Compact Size Unscented Tampons are recognized to not enhance the growth of *Staphylococcus aureus*. They do not increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1). They have no effect on culture pH. They do not alter the growth of normal vaginal microflora.

10. Performance Testing – Bench

The following testing has been performed to support substantial equivalence:

- Absorptive Capacity (Syngina)
- Fiber loss
- Cord strength
- Expulsion force of the applicator
- Microbiology batch testing (total viable count (TVC), presence of yeasts/moulds, *Candida albicans*, gram-negative bacteria, *Staphylococcus aureus*, *Pseudomonas aeruginusa*)

The results of this testing have shown that the performance of the subject device is equivalent to the predicates. Indeed, as for the predicates, testing gives similar results which are within the specifications previously defined for the predicates devices.

Fiber loss is less than 1 mg, Cord strength is less than 50N (same as predicate Roll Digital Tampon in viscose), Expulsion force of the applicator is less than the specification of 6N.

As for the predicates, the total viable count is less than 10 cfu/g of tampon and meets the specification of less than 200 cfu/g of tampon. The total presence of yeasts and moulds is less than 10 cfu/g of tampon and meets the specification of less than 20 cfu/g of tampon. As for the predicates, *Candida albicans*, gram-negative bacteria, *Staphylococcus aureus* and *Pseudomonas aeruginusa* are absent in 1g of tampon and meet the specifications of negativity.

The modifications have no impact on the technological performance and microbiology safety of the device.

11. Statement of Substantial Equivalence

As part of demonstrating safety and effectiveness of ONTEX Roll wadding plastic Applicator Compact size Unscented Tampons and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, ONTEX has completed a number of tests. The Roll wadding plastic Applicator Compact size Unscented Tampons meet all the requirements for biocompatibility, and microbiology and confirms that the output meets the design inputs and specifications.

It can be shown in this 510(k) submission that the difference between the Roll wadding plastic Applicator Compact size Unscented Tampons and the predicate devices do not raise any questions regarding its safety and effectiveness.

Design, principals of operation, performance characteristics and intended use between the Roll wadding plastic Applicator Compact size Unscented Tampons and the predicate devices are identical. Bench testing and standard microbiological controls demonstrate that the Roll wadding plastic Applicator Compact size Unscented Tampons is substantially equivalent to the relevant aspects of the predicate devices, in terms of technological performance and microbiological safety. The Roll wadding plastic Applicator Compact size Unscented Tampons, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2014

ONTEX BVBA
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Re: K132595
Trade/Device Name: ONTEX ROLL WADDING PLASTIC APPLICATORS COMPACT SIZE UNSCENTED TAMPONS
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: February 21, 2014
Received: February 18, 2014

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert P. Lerner -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

Indications for Use Statement

510(k) Number : K132595

Device Name: ONTEX ROLL WADDING PLASTIC APPLICATORS COMPACT SIZE UNSCENTED TAMPONS

Indications for Use:

The Ontex Roll wadding plastic Applicator Compact size Unscented Tampons are inserted into the vagina to absorb menstrual discharge.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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