

K120481



**510(k) Summary of Safety and Effectiveness**

As required by 21 CFR 807.92

JUL 13 2012

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Quality Control Manager

Date Prepared: July 10, 2012

Device name: Applicator tampon  
Non applicator tampon

Trade names: Lil-lets Silk Comfort Compact, Plastic Applicator,  
Lite, Regular, Super, Super plus and Ultra  
Lil-lets Non Applicator,  
Regular, Super, Super plus and Ultra

Common name: Unscented Tampon

Classification name: Unscented menstrual tampons (21 CFR 884.5470)

Predicate Devices: MAXIM Plastic Applicator and Non Applicator Tampons K080775

Device description: Lil-lets tampons are used to absorb menstrual fluid.  
Lil-lets series tampons come with a plastic applicator and without a plastic applicator in sizes: Lite, Regular, Super, Super plus and Ultra.  
Lil-lets tampons are made of commercial cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string.

Intended use: Lil-lets unscented menstrual tampon are intended for intravaginal absorption of menstrual or other vaginal discharge.  
This is the same intended use as current commercial tampons.

Technological characteristics: There are no differences between the technical characteristics of the Lil-lets tampons and the predicate characteristics of the substantially equivalent devices MAXIM tampons under K080775. All sizes of Lil-lets tampons without plastic applicator and all sizes of Lil-lets tampons with plastic applicator: Lite, Regular, Super, Super plus and Ultra have the same characteristics; they differ only in dimensions.



Non-Clinical Tests

Biocompatibility:

No additional testing was necessary because the materials of Lil-lets tampons are substantially equivalent to MAXIM Plastic Applicator and Non Applicator Tampons, K080775.

Characteristics	Standard
Preclinical Microbiology Tests	<ul style="list-style-type: none"><li>- Enhance the growth of <i>Staphylococcus aureus</i> (Zone of inhibition)</li><li>- Alter the growth of normal vaginal microflora (Zone of inhibition)</li><li>- Increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1)</li></ul>
Syngyna Testing	Syngyna testing was conducted in accordance to 21 CFR 801.430(f)(2) to verify that the subject tampons met absorbency ranges as specified in the regulation. The tampons are labeled in accordance to required ranges.
Physical and chemical tests	Internal method: <ul style="list-style-type: none"><li>- Fibre loss test</li><li>- Stability of digital tampons</li><li>- Withdrawal cord attachment test</li><li>- Expulsion force of applicator tampons</li></ul>

Conclusion:

The Lil-lets Silk Comfort Compact Plastic Applicator Tampons and Lil-lets Non Applicator Tampons are substantially equivalent to MAXIM Plastic Applicator Tampons and MAXIM Non Applicator Tampons approved for market under K080775.

Signed by Quality Control Manager  
Marjetka Kralj Kunčič, PhD



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 13 2012

Re: K120481  
Trade/Device Name: Lil-lets Comfort Compact Plastic Applicator Tampon &  
Lil-lets Non-Applicator Tampon  
Regulation Number: 21 CFR§ 884.5470  
Regulation Name: Unscented menstrual tampon  
Regulatory Class: II  
Product Code: HEB  
Dated: June 20, 2012  
Received: June 20, 2012

Dear Dr. Kunčič:

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.

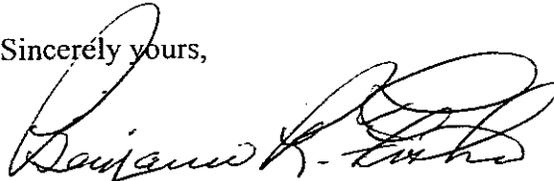
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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 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,



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

510K Number (if known):

K120481

Device Name:

Lil-lets Silk Comfort Compact Plastic Applicator Tampon & Lil-lets Non-Applicator Tampon

## Indications for Use:

The Lil-lets tampons (both types) are unscented tampons for:

- Women's personal hygiene with respect to intra vaginal absorption of menstrual or other vaginal discharge.
- The plastic applicator is for easing the placement of the tampon correctly into the vagina (only the Lil-lets Silk Comfort Compact Plastic Applicator Tampon).

Prescription Use \_\_\_\_\_ AND/OR Over-The Counter Use   X  

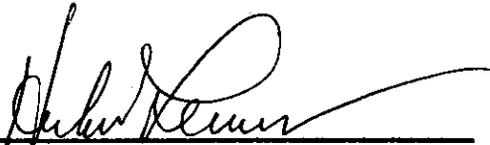
(Part 21CFR 801 Subpart C) (Optional Format 1-

2- 96)

(Part 21 CFR 801 Subpart O)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices

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Exhibit 117 006