May 30, 2018

Playtex Manufacturing, Inc.
% Danielle Vitale
Manager, Global Product Safety
Edgewell Personal Care
75 Commerce Drive
Allendale, NJ 07401

Re: K180167
Trade/Device Name: Playtex Stella™ Tampons
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: April 27, 2018
Received: April 30, 2018

Dear Danielle Vitale:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180167

Device Name
Playtex Stella™ Tampons

Indications for Use *(Describe)*
Playtex® unscented menstrual tampons are intended to be inserted into the vagina and used to absorb menstrual fluid.

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:

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# 510(k) Summary
# (K180167)

## 1. Submitter Information

Submitter: Playtex Manufacturing, Inc.
804 Walker Road
Dover, DE 19904

Contact Person: Danielle Vitale,
Manager, Global Product Safety
Phone: 201-785-8080
Fax: 201-785-8202
Email: Danielle.Vitale@edgewell.com

## 2. Date Prepared

May 29, 2018

## 3. Device Information

| | |
|---|---|
| Trade Name: | Playtex Stella™ Tampons |
| Common Name: | Unscented Menstrual Tampon |
| Regulation Number: | 21 CFR §884.5470 |
| Regulation Name: | Unscented Menstrual Tampon |
| Product Code: | HEB (Tampon, Menstrual, Unscented) |
| Regulatory Class: | II |

## 4. Predicate Device:

Playtex® (Scented and Unscented) Sport Fresh Balance™ Tampons (K132819) manufactured by Playtex® Manufacturing, Inc. The predicate device has not been subject to any design related recalls.

## 5. Device Description:

The subject devices, which are modified from the predicate devices, are unscented menstrual tampons consisting of a tampon (pledget with string) and an applicator. The tampons are made of rayon fiber and have absorbency ranges: regular (6-9 grams) and super (9-12 grams). The applicators are made of polyethylene and polypropylene and have four color versions.

## 6. Indications for Use

Playtex® unscented menstrual tampons are intended to be inserted into the vagina and used to absorb menstrual fluid.

## 7. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

The subject and predicate devices have the same intended use – to absorb menstrual fluid. The subject and predicate devices have the same tampons, but the subject devices have additional color versions

for the applicator. This difference in technological characteristics does not raise different questions of safety and effectiveness and can be evaluated by color safety studies.

**8. Summary of Non-Clinical Performance Testing**

The color leaching studies were conducted for new applicators using liquid chromatography-mass spectrometry (LC-MS) and gas chromatography-mass spectrometry (GC-MS). The results were analyzed along with Tolerable Intake (TI) analysis of each component in the colorant formulation using ISO 10993-17:2002.

In addition, the biocompatibility information provided in the predicate devices (K132819) was leveraged in the current submission to support substantial equivalence to the predicate device.

**9. Conclusion**

The subject and predicate devices have the same intended use and fundamental technological characteristics. The difference in technological characteristics between subject and predicate devices does not raise different questions of safety and effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate device.