



Food and Drug Administration
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December 18, 2015

Procter & Gamble
Lenore Faulhaber
Regulatory Affairs Manager
6110 Center Hill Ave.
Cincinnati, OH 45224

Re: K151413
Trade/Device Name: Always/Tampax bladder supports
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: Class II
Product Code: HHW
Dated: November 19, 2015
Received: November 20, 2015

Dear Lenore Faulhaber,

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 yours,


Benjamin R. Fisher -S

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

510(k) Number (if known)

K151413

Device Name

Always/Tampax bladder supports

Indications for Use (Describe)

For the temporary management of stress urinary incontinence in women

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
K151413

Submitter

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Contact Person

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Date prepared

December 11, 2015

Common Name

Intravaginal stress incontinence device

Classification Name

Vaginal Pessary (21 CFR 884.3575, Product Code HHW)

Proprietary Name

Always/Tampax bladder supports

Indications for Use/ Intended Use

For the temporary management of stress urinary incontinence (SUI) in women

Predicate Device

Improve Bladder Supports/TIPI OTC K131198; Manufactured by ConTIPI Ltd.

Device Description

The device is a single use vaginal pessary, inserted into the vagina, by the user, using a tampon-like applicator. The device is composed of a high density polyethylene core, a non-woven overwrap, and a withdrawal cord. The overwrap helps to facilitate ease of insertion and removal. The device is removed by a withdrawal cord made from tampon withdrawal cord material. Upon removal, the device is disposed of in a trash receptacle. The pessary is a single-use device. It is designed for daily use up to 12 hours in 24 hours. The device is available in one size and is sold over-the-counter.

Technological Characteristics of Subject Device Compared to Predicate

Comparison Element	510(k) Device	Predicate Tipi OTC [K131198]
Classification Name	Pessary, Vaginal	Pessary, Vaginal
Manufacturer	Procter & Gamble	ConTIPI, Ltd.
Indications for Use	For the temporary management of stress urinary incontinence (SUI) in women.	For the temporary management of stress urinary incontinence (SUI) in women.
Intended Population	Any women (18 and older) who have SUI symptoms	Women 21 years of age or older who have SUI
Mode of Action	Increases pressure through the anterior vaginal wall onto the urethra	Tension free, mid-urethral support
Wear Time	Up to 12 hours in a 24 hour period	Up to 8 hours in a 24 hour period
Insertion	Via a tampon-like applicator	Via a tampon-like applicator
Removal	Tampon-like withdrawal cord	Tampon-like withdrawal cord
Single Use?	Yes	Yes
Pessary Core Design	Shaped High Density Polyethylene core covered by a non-woven overwrap	Soft flexible silicone rubber, multiple armed cores covered by non-woven mesh
Sizing	Available in one size	Available in multiple sizes
Overwrap	Nonwoven	Nonwoven
Withdrawal Cord	Removal string	Removal string
Applicator	Tampon-like applicator	Tampon-like applicator

Summary of Non-Clinical Tests

Design Verification Assessment

Pessary Applicator Force

A quantitative method to measure pessary applicator expulsion using a semi-automated tester to measure tension and compression.

Retraction during Device Removal

Not applicable

Pessary Withdrawal Cord Anchor Strength

This procedure determines the maximum force required to break or detach the pessary withdrawal cord. Reference: Australian / New Zealand Standard (AS 2869-2008)

Removal String Integrity/ String Tensile Testing

Specified string properties (for example, Tensile Strength) are confirmed to meet finished product specifications. Reference Method: ASTM D2256 (1998)

Stiffness of Core/ Dimension Verification

Specified core properties (dimensions, weight and resin material properties) are confirmed to meet finished product specifications.

Biocompatibility Assessment

Test	Standard	P&G Device	FDA Recognition Number
Cytotoxicity	ISO 10993-5:2009: Biological evaluation of medical devices, Part 5: Tests for <i>in vitro</i> cytotoxicity. 2009-06-01.	Non-cytotoxic	2-153
Sensitization	ISO 10993-10:2010: Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization. 2010-08-01.	Non-sensitizing	2-174
Vaginal Irritation	ISO 10993-10:2010: Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization. 2010-08-01.	Non-irritating	2-174
Genotoxicity	N/A	Risk Analysis Approach	N/A
Acute Systemic Toxicity	N/A	Risk Analysis Approach	N/A
Subchronic Systemic Toxicity	N/A	Risk Analysis Approach	N/A
Chronic Systemic Toxicity	N/A	Risk Analysis Approach	N/A
Reproductive/ Developmental Toxicity	N/A	Risk Analysis Approach	N/A
Carcinogenicity	N/A	Risk Analysis Approach	N/A
Local Effects after Implantation	ISO 10993-6:2007: Biological evaluation of medical devices, Part 6: Tests for local effects after implantation. 2007-04-15.	No evidence of microscopic or macroscopic tissue reaction	2-177

Evaluation of Toxic Shock Syndrome Risk

The pessary was evaluated *in vitro* to determine if it enhances the growth of *Staphylococcus aureus*, increases the production of Toxic Shock Syndrome Toxin-1 (TSST-1), or alters the growth of normal vaginal microflora. Under the test conditions, the pessary device did not promote or inhibit either bacterial growth or TSST-1 toxin production.

Label Comprehension and Self-Selection

The labeling was assessed in a combined self-selection and label comprehension study. The study objectives were to evaluate self-selection and comprehension of targeted communication objectives from the external package labeling and Instructions for Use (IFU) that were different from the predicate device (K131198). Three cohorts were tested: 1) A population of women who may use product based on personal medical history, ages 18 and older; 2) A population of women who may use product based on personal medical history, ages 18 and older with low literacy; 3) A population of women who may use product based on personal medical history, ages 65 and older.

Summary of Clinical Tests

Two clinical studies were performed:

- **Safety study:** A randomized, 2-arm (pad control), single-blind (vaginal examiner), multi-center, 3-month safety study, in which safety was assessed by adverse events and physical examination, visual vaginal examinations, clean catch urine collection and vaginal swabbing at baseline, week 2, week 4, and week 12.

This study showed that the device was well-tolerated, with no serious AEs. The majority of the AEs that were observed were ‘mild’ and spontaneously resolved. The device showed minimal effect on the vaginal wall and surrounding structures, which is a particularly important finding for post-menopausal women who represented over 70% of the study population. This study shows that the device was well tolerated in, and used appropriately by, women with self-identified SUI.

- **Efficacy and safety study:** A single-arm, open label, multi-center, 4-week efficacy study (2-week baseline followed by a 2-week treatment period) that assessed the change from baseline for both pad weight gain and SUI episode frequency. A clinically meaningful improvement as a composite of the symptoms that are most relevant to the improved QoL for women was evaluated: 1) SUI episode frequency and 2) pad weight gain. Safety of the pessary was assessed by adverse events, clean catch urine collection and vaginal swabbing.

This study demonstrated that the single-use, disposable pessary was effective for women with SUI, and was safe and comfortable. The data show a statistically significant and clinically meaningful improvement in the symptoms that were most important to each woman, whether it was a reduction in SUI episode frequency, a reduction in pad load, or both. The study also showed that women were able to appropriately self-identify symptoms of SUI and appropriately self-administer the device, which is important for an OTC product.

Conclusion

The differences between Always/Tampax bladder supports and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Non-

clinical and clinical testing has demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. Therefore, Always/Tampax bladder supports are substantially equivalent to the legally marketed predicate device.