May 16, 2024

Watkins-Conti Products Inc.
% Adrienne Lenz
Principal Medical Device Regulatiory Expert
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, District of Columbia 20005

Re: K232525
Trade/Device Name: Yoni.Fit Bladder Support
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: Class II
Product Code: HHW
Dated: April 16, 2024
Received: April 16, 2024

Dear Adrienne Lenz:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn).

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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232525

Device Name
Yōni.Fit® Bladder Support

Indications for Use *(Describe)*
The Yōni.Fit® Bladder Support is intended for the temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.

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.

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Watkins-Conti Products

510(k) for Yōni.Fit® Bladder Support

K232525

510(k) SUMMARY

Submitter/Sponsor:

Watkins-Conti Products Inc.
3841 East Danforth Rd., Suite 109
Edmond, OK 73034

Contact Person:

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Watkins-Conti Products, Inc.
3841 East Danforth Rd., Suite 109
Edmond, OK 73034
Office: 1-405-330-3550

Date Prepared:

May 16, 2024

General Device Information:

Generic Device Name

Pessary, Vaginal

Tradename

Yōni.Fit® Bladder Support

Product Classification Codes

- Product Code – HHW (pessary, vaginal)
- Classification Panel – Obstetrical/Gynecological
- Device Class – 2
- Regulation Number and Name – 21 CFR § 884.3575 Vaginal pessary

Predicate Device:

Uresta™ Pessary (K083769)

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

Reference Device:

Poise Impressa (K131198)

1. INDICATIONS FOR USE

The Yōni.Fit® Bladder Support is intended for the temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.

2. DEVICE DESCRIPTION

The Yōni.Fit® Bladder Support is a vaginal pessary prescribed by a physician for single patient use for the temporary management of stress urinary incontinence. The device is intended for a single 30-day duration per patient. It can be worn for up to 12 hours in a 24-hour period and is reusable after washing with warm water and mild, oil-free soap. The device is a single-patient, multi-use medical device that will be provided non-sterile and requires reprocessing prior its first and subsequent uses. The rim of the Yōni.Fit® Bladder Support applies pressure against the urethra and bladder neck to support the bladder and urethra. The Yōni.Fit® Bladder Support is available in each of the following sizes: 34mm (Size 1), 38mm (Size 2), 42mm (Size 3), 45mm (Size 3.5), 48mm (Size 4), and 52mm (Size 5). The Yōni.Fit® Bladder Support is made of injection molded silicone (non-latex rubber) with no color additives.

Each package of the Yōni.Fit® Bladder Support comes with the following:

- 3 reusable Yōni.Fit® Bladder Supports for sizing
- Cleaning brush
- Storage case
- Instructions for Use

3. SUBSTANTIAL EQUIVALENCE

A comparison of the device characteristics between the Yōni.Fit® Bladder Support and the Uresta™ Pessary is shown in Table 1. The Yōni.Fit® Bladder Support and the Uresta™ Pessary have the same intended use. There are minor differences in technological characteristics between the Yōni.Fit® Bladder Support and the Uresta™ Pessary. These differences do not raise different questions of safety or effectiveness. Performance data, as discussed below, demonstrate that the Yōni.Fit® Bladder Support is as safe and effective as the Uresta™ Bladder Support. The two devices therefore are considered substantially equivalent.

Table 1: Comparison of Device Characteristics between the Yōni.Fit® Bladder Support and the Uresta™ Bladder Support (K083769)

Characteristic	Uresta™ Bladder Support (K083769)	Yōni.Fit® Bladder Support	Comparison
Indications for Use	For use in adult women, over 18 years of age, to prevent involuntary urine loss with physical activity (stress urinary incontinence) (SUI).	The Yōni.Fit® Bladder Support is intended for the temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.	Similar
Mechanism of Operation	Increases pressure through the anterior wall onto the urethra.	Increases pressure through the anterior wall onto the urethra.	Same

Characteristic	Uresta™ Bladder Support (K083769)	Yōni.Fit® Bladder Support	Comparison
Materials of Composition	Santoprene (non-latex thermoplastic rubber)	Silicone (non-latex rubber) with no color additives	Different
Shape and Structure	Bell shaped, flexible. • Tapered tip interacts with upper more horizontal portion of vagina and bell shape falls into place naturally under urethra. • No folding or manipulation of pessary required. • Handle allows for easy management.	Cone-shaped, flexible. • The rim of the Yōni.Fit® Bladder Support applies pressure against the urethra and bladder neck. • Collapses for insertion. • Handle allows for easy management.	Different
Wear Time	Up to 12-hours in a 24-hour period	Up to 12-hours in a 24-hour period	Same
Sterility	Non-sterile	Non-sterile	Same
Rx/OTC	Rx	Rx	Same
Use	Single patient use. Reusable. Removed daily.	Single patient use. Reusable. Removed daily.	Same
Sizes	Multiple sizes – 7 30 – 56 mm	Multiple sizes – 6 34 – 52 mm	Different
Use-life	1-year	30-days	Different
Cleaning	Use warm water and a mild, non-perfumed soap to wash. Rinse thoroughly with water after washing. Dry with a towel or cloth. Place in bottom unit of case and leave the case open to air dry.	Wash with warm water and a mild, scent free, oil-free liquid soap. Rinse with warm water to make sure all soap and material are removed. Air dry in a clean, dry place or use the optional Storage Case.	Similar

4. DEVICE PERFORMANCE DATA

4.1. Summary of Non-Clinical Performance Tests

4.1.1. Bench Tests

Bench performance tests confirmed the device met specifications for dimensions, fold force, fold width, fold height, pull tab strength, therapy force, and maximum force. The Poise Impressa (K131198) was used as a reference device to support the therapy force requirements of the Yōni.Fit®.

Cleaning validation studies were performed in accordance with FDA's 2015 guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, AAMI TIR12:2020, AAMI ST98:2022, and with ISO 10993-5 to validate the device cleaning procedures listed in the Instructions for Use.

Laboratory studies were performed to evaluate the impact of the device on Staphylococcus aureus growth and TSST-1 production, following FDA guidance for Menstrual Tampons and Pads: Information for Premarket Notification Submissions. These studies demonstrated that the Yōni.Fit® does not enhance TSST-1 production above the no product controls or marketed tampons and does not alter the growth of vaginal microflora, including TSST-1 producing S. aureus, as compared to no product controls.

4.1.2. Biocompatibility

The Yōni.Fit® Bladder Support has undergone biocompatibility evaluation and testing in conformance with ISO 10993-1:2018 and FDA's guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* The Yōni.Fit® Bladder Support is categorized as a surface device in contact with mucosal membrane for prolonged (>24 hours up to 30 days) contact duration. Cytotoxicity, sensitization, vaginal irritation, acute systemic toxicity, material-mediated pyrogenicity, and subchronic systemic toxicity tests were performed, and the results of the biocompatibility testing were acceptable.

4.2. Summary of Clinical Performance Tests

4.2.1. Summary of Clinical Testing

The clinical study, “Randomized, Comparator-controlled, Single Blinded, Multicenter Study Evaluating the Efficacy and Safety of Yōni.Fit® in Women with Stress Urinary Incontinence (SUI),” was conducted to evaluate the safety and effectiveness of the Yōni.Fit® Bladder Support in temporary management of SUI in women in comparison to a sham comparator device. This was a randomized, comparator-controlled, single blinded, multicenter crossover study in which participants from three US sites with SUI were enrolled in the study. Study participants included females 18 years of age or older diagnosed with SUI by both a cough supine test and ≥ 3 month history of experiencing SUI. Clinical study participants were randomized to either the Yōni.Fit® or a control device (Ring type pessary). After a brief training and fitting with the appropriate size of the device, each participant wore a study device for 12 hours per day. Participants wore incontinence pads

to measure any potential leakage, recorded voiding (urination) in diaries, and provided responses to questionnaires. At baseline (1-week post-randomization with no device), fitting (1 week after baseline), and efficacy evaluation (1 week after fitting), 12-hour pad weights, voiding diaries, and participant questionnaires were collected. After completion of the fitting and treatment period, the Yōni.Fit® subjects and comparator device subjects wishing to cross-over to the Yōni.Fit® entered a 4-week open-label follow-up phase of daily typical use.

A total of 58 participants (31 Yōni.Fit® and 27 control) were enrolled and randomized. Participants were between the ages of 30 – 71 years old in the treatment arm and 36 – 73 years old in the control-comparator arm. Of these, 5 postmenopausal participants were randomized in the treatment arm and 12 in the control-comparator arm, but a total of 7 postmenopausal participants were exposed to Yōni.Fit®. Other demographics of total study subjects included 2.2% (1) American Indian/Alaskan Native, 13.3% (6) Asian, 20% (9) Black/African American, 2.2% (1) Native Hawaiian/Pacific Islander, 55.6% (25) White/Caucasian and 6.6% (3) Not disclosed/Other. Fifty-six (56) participants completed the treatment phase and 54 continued to the open label phase. Forty-two (42) participants completed 30 days of safety follow-up and 38 participants completed 6 weeks of safety follow-up. There were four participants (2 Yōni.Fit®, 2 control) who had completely missing data for the efficacy evaluation phase. Participants with completely missing data for the efficacy evaluation phase were considered non- responders in the analyses and assumed to have less than a 50% reduction in their average 12-hour pad weights during the efficacy evaluation phase.

The primary effectiveness endpoint was a responder rate, defined as >50% reduction in mean 12-hour pad weights during the efficacy evaluation period compared to the baseline period. A statistically significantly higher percentage of participants experiencing more than a 50% reduction in their average 12-hour pad weights was observed with the Yōni.Fit® device compared to the control device. Of the participants randomized to use the Yōni.Fit®, 51.6% had a >50% reduction in 12-hour pad weight compared to 25.9% in the control group. The two-sided 95% confidence interval for the difference in the percentage of participants experiencing more than a 50% reduction in 12-hour pad weights between the control groups was 0.0235 to 0.504.

The primary safety endpoint was the incidence and nature of adverse events. The adverse event rate was 54.8% for participants with the Yōni.Fit® Bladder Support and 29.6% for Control participants. The most common adverse event was vaginal discomfort in 9 (29.0%) Yōni.Fit® Bladder Support participants compared to 5 (18.5%) Control participants. Among study participants experiencing adverse events, the severity was mild or moderate and there were no device-related serious adverse events. Vaginal bleeding was noted among 8 participants (4 postmenopausal participants) who wore the Yōni.Fit® Bladder Support and 1 in the control arm.

5. CONCLUSION

The results of the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device for the intended 30 days use of which clinical and non-clinical testing was performed. Therefore, the Yōni.Fit® Bladder Support and the Uresta™ Pessary are determined to be substantially equivalent.