



January 25, 2019

Rinovum Subsidiary 2, LLC  
Shaylee Masilunas, RAC  
Director of Regulatory, Clinical and Quality Affairs  
300 Oxford Drive, Suite 330  
Monroeville, PA 15146

Re: K183468  
Trade/Device Name: Revive Reusable Bladder Support  
Regulation Number: 21 CFR§ 884.3575  
Regulation Name: Vaginal Pessary  
Regulatory Class: II  
Product Code: HHW  
Dated: December 14, 2018  
Received: December 14, 2018

Dear Shaylee Masilunas:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 4, Subpart A) for combination products; 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Glenn B. Bell -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)

K183468

Device Name

Revive Reusable Bladder Support

Indications for Use (Describe)

The Revive bladder support is intended for 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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) SUMMARY

### Rinovum Subsidiary 2, LLC's Revive™ Reusable Bladder Support

**Submitter/Sponsor:**

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Suite 330  
Monroeville, PA 15146  
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**Contact Person:**

Shaylee Masilunas, RAC  
Director of Regulatory, Clinical, and Quality Affairs  
smasilunas@rinovum.com

**Date Prepared:**

December 14, 2018

**General Device Information**Generic Device Name

Intra-vaginal Stress Urinary Incontinence Device

Device Tradename

Revive Reusable Bladder Support

Product Classification Codes:

- Device Classification Name – Pessary, Vaginal
- Product Code – HHW
- Classification Panel – Obstetrical/Gynecological
- Device Class – 2
- Regulation Number – 21 CFR § 884.3575

**Predicate Device**

Proctor & Gamble Always/Tampax bladder supports (K151413)

**Reference Device**

ConTIPI Ltd. Improve Bladder Supports (K131198)

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## Intended Use/Indications for Use

The Revive bladder support is intended for temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.

## Device Description

The Revive bladder support reduces bladder leaks in women who are suffering from SUI by preventing or reducing unwanted urinary leakage. Use of the device is applicable for women who experience leakage when laughing, coughing, exercising, sneezing, etc. The device is not intended to treat women with urge incontinence. The shape of the Revive bladder support is designed to fit in the vaginal tract, and there is no sizing required. The device fits most users. The device can be worn daily for up to 12 hours. The Revive bladder support can be reused (and cleaned) for up to 31 times. Each packaged Revive bladder support device comes with the following:

- 1 Reusable Bladder Support
- 1 Reusable Applicator
- 1 Month Strings Supply
- Travel Case
- Instructions for Use

## Technological Characteristics

The Revive Reusable Bladder Support is a reusable and cleanable system that includes a silicone bladder support and a tampon-like reloadable applicator. A single-use disposable cotton string is assembled to the bladder support for easy, tampon-like removal from the vaginal cavity. The package will also include a set of 30 replacement strings, detailed Instructions for Use, and a device storage case. The bladder support and applicator components are to be cleaned after each use. The device is available in only one size and is sold over the counter.

## Performance Data

### *Summary of non-clinical tests*

#### **Removal string to pessary retention force**

This method determines the force required to separate the string from the pessary. The product is confirmed to meet specification.

#### **Pessary from applicator extraction force**

This method determines the force required to extract the pessary from the applicator. The product is confirmed to meet specification.

#### **Tensile strength of string**

This method determines the force required to break the withdrawal removal string. The product is confirmed to meet specification.

#### **Retraction force of pessary removal**

This method determines the force required to remove the pessary, using the withdrawal removal string, from the vaginal cavity. The product is confirmed to meet specification.

**Dimension verification**

Specified product dimensions are confirmed to meet finished product specifications.

*Biocompatibility Assessment*

Revive Component	ISO Standard	Test	Results
Pessary String Applicator	10993-5	Cytotoxicity Study Using the ISO Elution Method	Non-cytotoxic
Pessary String Applicator	10993-10	ISO Guinea Pig Maximization Sensitization Test	Non-sensitizer
Pessary String Applicator	10993-10	ISO Vaginal Irritation Study in Rabbits	Non-irritant
Pessary String	10993-11	Material Mediated Pyrogenicity in Rabbits	Non-pyrogenic
Pessary String	10993-3	Genotoxicity: Bacterial Reverse Mutation Study	Non-mutagenic
Pessary String	10993-3	Genotoxicity: Mouse Lymphoma Assay	Non-mutagenic
Pessary String	10993-18	Chemical Characterization	Outlined in Biological Risk Assessment

A biological risk assessment was completed and indicated that the likelihood of a toxic effect is negligible and that the Revive™ device can be considered safe for use as intended. No further testing was recommended.

*Evaluation of Toxic Shock Syndrome Risk*

The device was evaluated to determine that it does not enhance the growth of *Staphylococcus aureus* and does not increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1). Under the test conditions, the Revive bladder support did not promote or enhance the bacterial growth or toxin production.

*Summary of Clinical Testing*

A safety and efficacy study of the Revive Bladder Support was conducted. This clinical study was conducted as a non-IDE, Non-Significant Risk study, and was registered with [clinicaltrials.gov](http://clinicaltrials.gov). In this interventional, multicenter study, women underwent a baseline phase, as well as a treatment phase where they wore the investigational product. Device efficacy was evaluated through pad weight gain reduction, leakage reduction, and improvement in quality of life analysis. Safety was assessed by an evaluation of adverse events and other safety outcomes, such as vaginal swab and urinalysis results.

This study showed that the Revive bladder support was effective, well tolerated, and safe for use with no serious adverse events reported. During the clinical study, there was a total of 40 adverse events reported. Thirty-six were classified as mild. The most common adverse events that participants experienced throughout this study was vaginal pain and vaginal spotting. All adverse events were reviewed by a third-party adjudicator for consistent reporting and classification using Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. Vaginal swabs and urinalyses were also performed to evaluate if the product caused any significant negative changes in the vaginal microflora or urinary tract health, respectively. Only one participant tested positive for yeast cells after the treatment phase and was asymptomatic and not treated. Two participants screened positive in the urinalysis at final visit, however both participants were asymptomatic.

Statistically significant improvement in leakage volume and number of leakage episodes while wearing the Revive device was observed. 53% of the participants showed a >50% improvement in pad weight gain compared to baseline phase. Additionally, participants experienced an average 56.7% reduction in the number of leakage episodes per day. Compared to baseline, women reported a significant improvement in their quality of life. The study also showed that women were able to appropriately identify symptoms of SUI and determine in the device was a proper fit.

A responder analysis was performed, where a responder was defined as achieving >50% reduction in pad weight gain and/or >50% reduction in leakage episodes. Results indicated that 71% of participants achieved a clinically meaningful reduction in leakage episodes, pad weight gain, or both. The percentage of responders is greater as compared to the predicate device.

#### *Self-Selection, Labeling Comprehension, and Simulated Use*

As mentioned above, the clinical safety and efficacy study was conducted to support an OTC indication for use, as well as contribute to labeling comprehension. Self-selection was evaluated through the completion of a “Fit Test” during the screening process, in which the participants independently inserted a device using the Instructions for Use without physician guidance. Self-selection was also evaluated by participants’ ability to identify with SUI symptoms without a formal diagnosis prior to enrolling in the study. Additionally, this study contributed to labeling comprehension as participants used the Instructions for Use throughout the duration of the treatment phase.

Multiple rounds of summative testing were completed in the form of Labeling Comprehension, Selection and Simulated Use studies. This testing was performed to evaluate the appropriateness of the Instructions for Use and package labeling to support an OTC indication for use. The last round of summative testing was also used to validate the usability of the reusable device design. A diverse population of women in race, ethnicity age, and literacy rates participated.

#### **Substantial Equivalence**

The Revive Reusable Bladder Support has the following similarities to the previously cleared predicate device Always/Tampax bladder supports (K151413) and reference device Improve Bladder Support (K131198):

- Same general intended use
- Similar indications for use
- Same operating principle
- Similar materials
- Similar performance characteristics

The following modifications have been made to the Revive Reusable Bladder Support compared to the predicate device:

- The Revive bladder support and applicator are designed and validated to be reusable.
- The Revive bladder support does not include a fabric or mesh overwrap.

Comparison Element	PREDICATE DEVICE:	REFERENCE DEVICE:	SUBJECT DEVICE:
	Tampax/Always Bladder Supports K151413	Improve Bladder Support (Poise Impressa) K131198	Revive Bladder Support Stress Incontinence Device
INTENDED USE/INDICATIONS FOR USE STATEMENT	For the temporary management of stress-urinary incontinence in women.	The IMPROVE BLADDER SUPPORT is an over-the-counter device intended for the temporary management of stress urinary incontinence (SUI) in women.	The Revive bladder support is intended for temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.  (Unchanged from K151413 and K131198)
PATIENT POPULATION	Women $\geq$ 18 with SUI symptoms	Women $\geq$ 21 with SUI	Women $\geq$ 18 with SUI symptoms (Unchanged from K151413)
INTENDED ENVIRONMENT FOR USE	Home Use	Home Use	Unchanged from K151413 and K131198
SINGLE USE?	Yes	Yes	No. The Revive Bladder Support is reusable for 31 days.
WEAR TIME	Up to 12-hours in a 24-hour period	Up to 8-hours in a 24-hour period	Up to 12-hours in a 24-hour period (Unchanged from K151413)
DEVICE DESIGN	The Tampax/Always Bladder Support consists of a shaped high-density polyethylene core covered by a non-woven wrap with a tampon-like withdrawal cord, loaded into an applicator.	The Improve Bladder Support consists of a flexible silicone rubber core covered with mesh with a removal string, loaded into an applicator.	The Revive™ system consists of a reusable silicone bladder support (does not include an overwrap), with a removal string and a reusable, tampon-like applicator. The string is single-use disposable. Replacement strings are provided.



Comparison Element	PREDICATE DEVICE:	REFERENCE DEVICE:	SUBJECT DEVICE:
	Tampax/Always Bladder Supports K151413	Improve Bladder Support (Poise Impressa) K131198	Revive Bladder Support Stress Incontinence Device
MECHANISM OF ACTION	Increases pressure through the anterior wall onto the urethra.	Tension free, mid-urethral support for the temporary management of stress urinary incontinence (SUI).	Tension-free, mid-urethral support for the temporary management of stress urinary incontinence (SUI).
SIZES	1 size	3 size	1 size (Unchanged from K151413)
MATERIAL	Bladder support - High-density polyethylene core with a non-woven overwrap  String – cotton-like  Applicator - plastic	Bladder support - Silicone rubber core covered with a non-woven mesh  String – cotton-like  Applicator – plastic	Bladder support – Silicone rubber  String – Cotton  Applicator - low-density polyethylene

**Conclusion**

The performance and technological characteristics of the Revive Reusable Bladder Support are substantially equivalent to the predicate device Always/Tampax bladder supports (K151413) and reference device Improve Bladder Support (K131198). The differences described above do not raise new issues of safety or effectiveness.