

**510(k) SUMMARY  
ConTIPI LTD's IMPROVE BLADDER SUPPORT**

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

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**AUG 27 2013**

Date Prepared: August 26, 2013

**Name of Device and Name/Address of Sponsor**

IMPROVE BLADDER SUPPORT  
ConTIPI Ltd.  
2 Alon Ha'Tavor St.  
Caesarea Industrial Park 38900  
POB 3135, Israel

**Common or Usual Name**

Intra-vaginal stress incontinence device

**Classification Name**

Vaginal pessary

**Predicate Devices**

ConTIPI Ltd. TIPI (K060526)

**Intended Use / Indications for Use**

The IMPROVE BLADDER SUPPORT is an over-the-counter device intended for the temporary management of stress urinary incontinence (SUI) in women.

**Device Description and Technological Characteristics**

The IMPROVE BLADDER SUPPORT device is a single use vaginal pessary, inserted into the vagina, by the user herself, using an applicator similar to a menstrual tampon applicator. The device comprises of a flexible silicone rubber core, covered with a non-woven mesh, and a

removal string. Once inserted into the vagina, the core and cover of the device provides tension free mid-urethral support for the temporary management of stress urinary incontinence (SUI). After a maximum of 8 hours of use in a 24 hours period, the device should be removed from the vagina using its pull string and discarded.

### **Comparison to Predicate Device**

The IMPROVE BLADDER SUPPORT is a modification to its predicate, the cleared ConTIPI TIPI vaginal pessary device, and is substantially similar to its predicate device. While the predicate TIPI device was cleared for prescription use, the IMPROVE BLADDER SUPPORT is indicated for over-the-counter (OTC) use.

The designs of the subject and predicate versions of the device are substantially similar, with only minor modifications to the device materials, sizes and shape. Both the IMPROVE BLADDER SUPPORT and the predicate consist of a flexible silicone rubber core covered with mesh, an applicator and removal string and have very similar dimensions, materials, and performance. Minor changes have been made to IMPROVE BLADDER SUPPORT materials and shape as follows: replacing the core material with a similar medical silicon material; change in the cover mesh and removal string materials; slight change to core edges; a color has been added to the applicator; applicator and core shape and dimensions were slightly changed. These changes were made to improve manufacturability and promote patient comfort.

Additionally, the labeling materials of the IMPROVE BLADDER SUPPORT and the predicate are substantially the same but the labeling for the IMPROVE BLADDER SUPPORT was updated with self-selection information and is designed to conform to FDA's guidance on labeling for OTC devices.

### **Performance Data**

The following testing was performed to confirm that the subject device met its specifications and demonstrates substantial equivalence to the identified predicate device:

- Design verification testing to confirm that the subject device met its specifications and was substantially equivalent to the specifications of the predicate device. This testing included the following:
  - Force required to push a device out of the applicator (insertion force)
  - Retraction during device removal
  - String detachment force
  - Removal string integrity
- Bench testing to evaluate the force exerted on the vaginal wall in comparison to the predicate device
- Subject device's potential contribution to the development to *S. aureus* and TSST-1 when used as intended

- Biological Evaluation: The subject device has undergone the following biocompatibility tests:

Test	Standard	Conclusion
Cytotoxicity	ISO 10993-5:2009, 2 <sup>nd</sup> edition	Non-cytotoxic
Sensitization	ISO 10993-10:2010, 3 <sup>rd</sup> edition	Non-sensitizing
Vaginal Irritation	ISO 10993-10:2010, 3 <sup>rd</sup> edition	Non-irritating
Acute Systemic Toxicity	ISO 10993-11:2006, 2 <sup>nd</sup> edition	No evidence of systemic toxicity
Local Effects after Implantation	ISO 10993-6:2007, 2 <sup>nd</sup> edition	No evidence of tissue reactions relevant to actual use

- Shelf life study intended to establish that the IMPROVE BLADDER SUPPORT (subject device) retains its properties, in terms of microbiological load and performance, throughout its stated shelf life

In all instances the subject device met its specifications and demonstrated substantial equivalence to the predicate device.

### Clinical Testing

Clinical testing was necessary to support the change from prescription use to over-the-counter use of this device due to concerns that this change could potentially affect the safety profile of the device. To reduce the level of new clinical testing that was required to support clearance of the OTC device, the clinical study used to demonstrate safety and effectiveness of the predicate TIPI device was leveraged along with the new bench studies described above and a limited R&D supporting clinical evaluation. In addition, the change from prescription to OTC use required a demonstration that women could appropriately understand the contraindications for use (*i.e.*, who would and would not be appropriate users of the device) and comprehend the instructions for use. The following studies were conducted to address these concerns:

- A limited R&D supporting clinical evaluation to evaluate device safety and efficacy in comparison to the predicate device was performed. The subject device was evaluated in a limited patient population in a clinic setting. The results from the subject device were compared to those obtained using the predicate device and no device from the same patient population. The results showed substantially equivalent performance between the subject and predicate devices.

All adverse events were considered to be minimal, temporary and resolved without medical treatment and no sequelae.

- A multicenter, prospective, randomized, controlled, cross-over study to assess changes in vaginal microflora while using the IMPROVE BLADDER SUPPORT in the temporary

management of SUI in females was conducted. A total of 45 subjects completed the study. All screened patients were randomized between two groups. One group used the pessary for the first 30 days (or one menstrual cycle) followed by pads (control) for the second 30 days (or second menstrual cycle). The other group used the pads first then the pessary. A clinical evaluation of vaginal microflora was completed before and after each phase. The results demonstrate no clinically significant change in vaginal microflora occurred following the use of the IMPROVE BLADDER SUPPORT and no meaningful change in microflora compared to the control (pad only). No serious adverse events were observed. The data also show that there were few adverse events which were generally mild, anticipated and resolved without medical intervention. The most frequently observed device related adverse effects included discomfort, spotting, bleeding and urinary tract infection. Subanalyses were conducted by race, menopausal status and hormone replacement therapy (HRT) use. The populations of African American, Hispanic and HRT users were too small to draw meaningful conclusions about them, but do not appear to show adverse effects of use.

- Following several preliminary studies to evaluate and refine the labeling, a selection and labeling comprehension study was performed. The objectives were to assess the ability of users to read the labeling and determine the appropriate user of the product and whether key concepts in the labeling were understood. The patient population was divided into three sub-groups comprising a low literacy population, general population and elder population. There were 15 women in each group. In the selection study, participants were required to read the exterior packaging and were then questioned by a moderator who posed different clinical scenarios to determine whether the participant could appropriately determine whether the woman in each scenario should use the product. The labeling comprehension study required that the participant read the instructions for use. The moderator then asked the participant questions to determine the participant's understanding of key points. On average, the participants in the selection study were able to correctly identify the appropriateness of the device 92% of the time. The participants in the labeling comprehension study were able to provide a correct answer 96% of the time. In both studies, the lowest performance was from the low literacy group; however, their results were still acceptable as they did not pose any additional risk to the user.

### **Substantial Equivalence**

The IMPROVE BLADDER SUPPORT is as safe and effective as the legally cleared predicate device (K060526-ConTIPI TIPI vaginal pessary). The IMPROVE BLADDER SUPPORT has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The IMPROVE BLADDER SUPPORT is indicated for over-the-counter use, however, this modification in the indications for use and the labeling does not alter the therapeutic effect of the predicate device. The IMPROVE BLADDER SUPPORT is substantially equivalent to the identified predicate device in terms of overall design, principles of operation, components and configuration, and the technological characteristics. The subject device incorporates minor differences in materials, sizes and shape to improve manufacturability and promote user comfort. Comparative bench testing and clinical data demonstrates substantially equivalent performance of the IMPROVE BLADDER SUPPORT and the predicate device. The minor technological differences between the IMPROVE BLADDER SUPPORT and

the predicate device raise no new issues of safety or effectiveness. Thus, the IMPROVE BLADDER SUPPORT is substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

August 27, 2013

ConTIPI Ltd.  
% Jonathan Kahan  
Partner  
Hogan Lovells US, LLP  
555 Thirteenth St., NW  
Washington, DC 20004

Re: K131198  
Trade/Device Name: IMPROVE BLADDER SUPPORT  
Regulation Number: 21 CFR 884.3575  
Regulation Name: Vaginal Pessary  
Regulatory Class: Class II  
Product Code: HHW  
Dated: July 29, 2013  
Received: July 29, 2013

Dear Jonathan Kahan:

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 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>. 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,

**Herbert P. Lerner -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

**Indications for Use Statement**

510(k) Number (if known): K131198

Device Name: IMPROVE BLADDER SUPPORT

Indications for Use:

The IMPROVE BLADDER SUPPORT is an over-the-counter device intended for the temporary management of stress urinary incontinence (SUI) in women.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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**Herbert P. Lerner -S**

(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices      K131198  
510(k) Number \_\_\_\_\_