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510(k) Summary

Non-Confidential Summary of Safety and Effectiveness
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15-May-06

JUN - 9 2006

ConTIPI Ltd.
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Official Contact -- Nir Sinai – Project Manager

Proprietary or Trade Name –

Common/Usual Name – Intra-vaginal stress incontinence device

Classification Name – Vaginal pessary

Device --

Predicate Devices -- Johnson & Johnson – Introl ® - Bladder Neck Support
K930618 and K965040

Device Description –

a device which is placed intra-vaginally to provide mid-urethral support. The soft, flexible device is inserted via an applicator, looks like a tampon applicator, and once placed in the vagina, expands to provide mild tension on the vaginal walls. It is has flexible arms that continue to provide support during normal body movement. It is removed via a pull string, like a tampon. It is single use, disposable and may be worn up to 8 hours at a time.

It is available in multiple sizes to accommodate differences in vaginal anatomy and severity of urine leakage.

Indications for Use – indicated for temporary management of genuine (mild, moderate and severe) stress urinary incontinence in females.

Patient Population -- designed to be used by any woman, who suffers from stress urinary incontinence.

Environment of Use – No limitations

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Contraindications -- Patients should not use if:

- Vaginal infection or lacerations are present
- Urinary tract infections
- Severely atrophic vagina
- Recovering from recent vaginal surgery
- Have difficulty inserting a vaginal tampon
- Abnormal vaginal bleeding
- During monthly menstruation period
- During coitus
- Consult your doctor regarding use during pregnancy

Clinical Testing Effectiveness and Safety --

A fifty (50) participant safety and efficacy study was performed. It measured objective and subjective end-points.

Objective Efficacy end-point

- Reduction in pad weight – Objective at least a 70% reduction
  - 94% of participants obtained % reduction of over 70% ($p<0.001$), mean % reduction 86±9% (with high range of 59-98%), and a specific frequency distribution showed that 80% of patients had >80% reduction of Δ pad weight.

Subjective Efficacy end-points

- Participant's perception of being dry
- 92% considered themselves dry when compared to the first week and the last few days of use
- Leak Score - Quality of Life (QoL) questionnaire the total score, decreasing from 21.26 to 5.3, pre-trial vs. post-trial, respectively.

Safety Testing

- We monitored all participants for any problems and adverse events.
- The number of reported adverse events was 6.6% which is lower than other predicate study results.
- Biocompatibility testing per ISO 10993-1 has been demonstrated.

Substantial Equivalence –

The device based upon a comparison to the predicate and clinical testing has been demonstrated that it is substantially equivalent.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 9 2006

ConTIPI Ltd.
% Mr. Paul E. Dryden
Regulatory Consultant
ProMedic, Incorporated
6329 W. Waterview Ct.
MCCORDSVILLE IN 46055-9501

Re: K060526
Trade/Device Name: Vaginal Pessary
Regulation Number: 21 CFR § 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: HHW
Dated: May 15, 2006
Received: May 16, 2006

Dear Mr. Dryden:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K060526

Device Name: Vaginal Pessary device

Indications for Use: Vaginal Pessary device is indicated for temporary management of genuine (mild, moderate, and severe) stress urinary incontinence in females.

Vaginal Pessary device is designed to be used by any woman, who suffers from stress urinary incontinence.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060526