



ConvaTec

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AUG 19 2011

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**510(k) SUMMARY**

**Subject Device:** VITALA™ Contenance Control Device

**Date Prepared:** May 12, 2011

**Applicant:** ConvaTec Inc.  
200 Headquarters Park Drive  
Skillman, New Jersey 08558

**Contact:** Charles Ryan  
Associate Director, US Regulatory Affairs  
Tel: 908-904-2500  
Fax: 908-904-2235

**Device Trade Name:** Vitala™ Contenance Control Device

**Classification Name:** Ostomy Pouch and Accessory (ref. 21 CFR 876.5900;  
Product Code EZQ)

**Device Class:** Class I

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**Predicate Device Trade Name:** Vitala™ Contenance Control Device

**Classification Name:** Ostomy Pouch and Accessory (ref. 21 CFR  
876.5900; Product Code EZQ)

**Device Class:** Class I

**510(k) Substantial Equivalence:** K102536 – determined substantially equivalent on  
December 1, 2010

K083785 – determined substantially equivalent on  
April 2, 2010

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The Vitala™ Contenance Control Device is a pouchless ostomy device consisting of a self-inflating Air Seal which contacts a stoma and is held against the stoma with a low pressure, allowing flatus to be deodorized and vented while retaining stool. The Air Seal contains a soft foam insert that expands to fill the Air Seal, causing the Air Seal to



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expand with it. As it expands, the Air Seal gently contacts the stoma and conforms to the shape of the stoma, and is held against the stoma with a low pressure. The Air Seal will re-inflate to remain in contact with the stoma if the stoma retracts or moves away from the Air Seal.

The Vitala™ Contenance Control Device also includes an expandable container to collect stool during removal of the device. This single use device is designed to be used only with a 1 3/4" (45mm) or 2 1/4" (57mm) ConvaTec Natura® skin barrier, and will accommodate a range of stoma diameters.

The Vitala™ Contenance Control Device is indicated for individuals with end colostomies. The device is not intended for use until the abdomen and peristomal area have fully healed from bowel surgery (until 6 weeks post surgery), or for use with a stoma protrusion greater than 2 cm (when lying down). The device should also not be used in individuals with end colostomies with a history of chronic liquid stool.

This 510(k) notification concerns a design modification for the Vitala™ Contenance Control Device to allow its use with ConvaTec Moldable Technology™ skin barriers.

ConvaTec has performed additional non-clinical, bench testing to assess the safety and effectiveness of the design modification (the addition of the air seal cap), which allows expanded compatibility of the Vitala™ Contenance Control Device when used with ConvaTec Moldable Technology™ skin barriers. Such testing included the following:

- Air Bag Leak Rate
- Air Flow
- Inflation Time
- Foam Pressure

ConvaTec has performed a clinical study to assess the safety and effectiveness of the modified design of the Vitala™ Contenance Control Device and its compatibility with ConvaTec Moldable Technology™ skin barriers.

#### Clinical Study Summary:

A non-randomized, open-label, multi-center clinical study was conducted in the USA. The study was initiated on September 17, 2010 and completed on November 11, 2010, with a primary objective to assess the safety of the Vitala™ Contenance Control Device when used with currently marketed ConvaTec Natura® moldable skin barriers featuring Stomahesive® or Durahesive® technologies in flange sizes of 45mm and 57mm, depending on the needs of the subject as determined by the investigator, during 12 hours of daily wear.

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The planned methodology was to enroll 25 subjects with an end colostomy of at least 12 weeks duration with formed or semi-formed effluent who had a stoma that protruded no more than 2cm at rest (supine/lying down on the back), a willingness to wear a moldable skin barrier and an ability to complete self-care.

A total of 28 subjects were enrolled in this study across four study centers in the USA. Eight subjects who were moldable skin barrier users at baseline and 20 subjects who were non-moldable users at baseline were enrolled into the study. Twenty-four subjects (85.7%) completed the study while four subjects (14.3%) discontinued from the study. Overall, 27 subjects wore the Vitala™ device.

In general, 91% of subject responses rated their use of the Vitala™ device as either “good” or “very good” in its ability to restore continence. The majority of subject responses (54%) rated the Vitala™ device as “very good” in restoring continence. There were only six subject responses (8%) that rated it “poor” and only one subject response (1%) rated it “very poor.” Additionally, the majority of subject responses (76%) stated that the Vitala™ device was their preferred method of ostomy management.

Overall, the rate of adverse events (AEs) during the Moldable Stage (where subjects used Convatec Natura® moldable skin barrier products prior to use of the Vitala™ device) was 0.003 and during the Vitala™ Stage it was identified at 0.014 per patient per day. Influenza and erythema were the most commonly reported AEs (two subjects, 7.4%). Three subjects (11.1%) had AEs that were considered moderate in severity during the Vitala™ wear period. One subject (3.7%) in the Moldable Stage had an AE (hypersensitivity) that was considered related to the skin barrier while two subjects (7.4%) in the Vitala™ Stage had AEs (erythema) that were related to the study device.

Stoma vascularity results provided no evidence of any changes in stoma oxygen saturation (SO<sub>2</sub>) or the development of hypoxic regions in the stoma and hyperoxic regions in the stoma as a result of wearing the Vitala™ device with Convatec Moldable Technology™ skin barrier products.

In conclusion, safety results therefore showed no serious adverse events and no abnormal findings during the Vitala™ Stage. No stoma related or gastrointestinal related AEs were reported that were related to the Vitala™ device. Stoma vascularity results provided no evidence of any changes in stoma SO<sub>2</sub> or the development of hypoxic regions in the stoma as a result of wearing the Vitala™ device. The Vitala™ device demonstrated continence during 12 hour wear based on both objective and subjective measurements when worn with moldable products. Any leakage rates were low during the Vitala™ Stage and identical to

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the Moldable Stage. Subject responses showed that subjects found the Vitala™ device easy to use with moldable skin barriers. Odor prevention and stoma noise prevention also improved in the Vitala™ Stage as compared to the Moldable Stage. The majority of subjects also stated that the Vitala™ device was the preferred method of ostomy management.

Overall, results from this study indicate that the Vitala™ device with its new modifications is safe and performs as expected when worn up to 12 hours daily with Convatec Moldable Technology™ skin barrier products.

### **Indications For Use**

The VITALA™ Contenance Control Device is a single-use device intended to prevent the release of stool from an end colostomy while allowing any flatus from the stoma to be deodorized and released.

To be used only with a 1 ¾ in. (45 mm) or 2 ¼ in. (57 mm) Convatec NATURA® skin barrier.

### **Overall Conclusions**

There are no significant differences in the intended use between the subject and predicate Vitala™ Contenance Control Devices. The Vitala™ device is non-invasive to the stoma, and has demonstrated substantial equivalence as well as safety and effectiveness through use in clinical studies and vascularity testing of the stoma.

Based on the evidence provided, we propose that the modified Vitala™ Contenance Control Device can be used safely and effectively for individuals with end colostomies to prevent the release of stool from an end colostomy, when used with Convatec Moldable Technology™ skin barriers.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Mark R. Jakubowski  
Manager, Regulatory Affairs  
ConvaTec Inc.  
200 Headquarters Park Drive  
SKILLMAN NJ 08558

AUG 19 2011

Re: K111365

Trade/Device Name: VITALA™ Continenence Control Device  
Regulation Number: 21 CFR§ 876.5900  
Regulation Name: Ostomy pouch and accessories  
Regulatory Class: I  
Product Code: EZQ  
Dated: August 12, 2011  
Received: August 15, 2011

Dear Mr. Jakubowski:

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

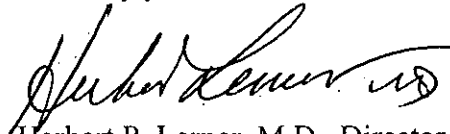
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adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, M.D., Director (Acting)  
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): Not Yet Assigned **K111365**

Device Name: VITALA™ Continence Control Device

**Indications For Use:**

The VITALA™ Continence Control Device is a single-use device intended to prevent the release of stool from an end colostomy while allowing any flatus from the stoma to be deodorized and released.

To be used only with a 1 3/4 in. (45 mm) or 2 1/4 in. (57 mm) ConvaTec NATURA® skin barrier.

Prescription Use   
(21 CFR 801 Subpart D)

AND/OR

Over the Counter Use   
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
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