K083785
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APR - 2 2010

SECTION 5: 510(k) SUMMARY

VITALA™ Continence Control Device

Applicant:	ConvaTec Inc. 200 Headquarters Park Drive Skillman, New Jersey 08558
Contact:	Marilyn Konicky Associate Director, US & International Regulatory Affairs 908-904-2541 Fax: 908-904-2235 Email: marilyn.konicky@convatec.com
Device:	Vitala™ Continence Control Device
Classification Name:	Ostomy Pouch and Accessory
Device Class:	Class I
Product Code:	EZQ - C.F.R. Section 876.5900

Substantially Equivalent Device: Coloplast Conseal Colostomy Continence System (K863830)

The Vitala™ Continence Control Device is a pouchless ostomy device consisting of a self-inflating Air Seal which contacts the 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 inserts that expands to fill the Air Seal, causing the Air Seal to 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. This 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™ Continence 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 ¾" (45mm) or 2 ¼" (57mm) ConvaTec SUR-FIT Natura® skin barrier, and will

accommodate a range of stoma diameters. The device is designed to be worn up to eight hours per day.

The Vitala™ Continence 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 (typically 6-12 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. ConvaTec Moldable Technology™ skin barriers or convex products should not be used with the Vitala™ device.

The Vitala™ Continence Control Device evolved through several concept designs, which were studied in six Phase II or Phase III clinical trials (see Section 20) prior to the determination of the final product design.

During the early device development, ConvaTec communicated with the U.S. FDA seeking advice on predicate information, if the device would require a 510(k) filing, and the appropriate classification of the device. During this early stage of development, the Vitala™ device included a hand-held, battery powered electric pump to inflate the airbag to a pressure of 15-23 mmHg after application to the skin barrier. Telephone conversations with FDA indicated that a 510(k) for Vitala™ should be filed to review any potential concerns of pressure on the stoma. According to the FDA, if the device did not include a pump, this would be exempt from 510(k). ConvaTec has eliminated the pump from the design of the product, but has decided to file a 510(k) for the Vitala™ Continence Control Device to establish safety and efficacy. In addition, microbiology studies and vascularity testing of the stoma was studied in the clinical trial for the most recent prototype design device. No issues of the stoma were identified.

A brief Summary of the Clinical Trials conducted on the various designs of the Vitala™ Continence Control Device (previously known internally within ConvaTec as PAMS) is provided; more complete clinical information is provided in Section 20.

Vitala™ Clinical Trial Summary

ConvaTec has performed six Phase II and one Phase III clinical trials on the evolving concepts of the Pneumatically Activated Membrane Seal (Vitala™) device, previously referred to internally within ConvaTec as PAMS.

Study #1

The PAMS prototype device for concept evaluation was designed to mate with a marketed 57mm SUR-FIT® AUTOLOCK™ Flexible Skin Barrier with Flange. The air bag within the PAMS device was inflated by a detachable manual thumb operated pump, which also included an electronic airbag pressure gauge. An integral filter allowed the

release of deodorized flatus. A closed cell foam gasket sized to fit around the stoma was used with the device.

Study #2

The previously used closed cell foam gasket placed around the stoma during device application was replaced by an absorptive foam ring in the prototype device in this Phase II study. In addition to the 57mm flange device, a 45mm flange version of the prototype device was developed for use in this study to accommodate a wider range of stoma sizes. No other changes were made to the prototype device since the previous trial.

The study found that the absorptive foam ring was not necessary and was eliminated for subsequent studies.

Study #3

The device used in this trial was the same as the device used in Study #2.

A third Phase II trial using both Stomahesive® and Durahesive® wafers as the skin barriers was conducted to evaluate the performance of the device without the absorptive foam ring. This trial also used two different airbag inflation pressures, 15mm Hg and 20mm Hg.

Study #4

A new device, in 45mm and 57mm flange sizes, was designed which was appropriate for manufacture and intended for market. This device included a new coupling system designed to be compatible with SUR-FIT Natura® wafers (skin barriers). Other new components included the cap with filter subassembly and the carrier with airbag subassembly. A hand-held, battery powered electric pump was used to inflate the airbag to a pressure of 15-23 mmHg after application to the Natura wafer.

There were no device related safety issues, but ConvaTec decided to stop the study because of high leakage rates due to partial or complete disconnection of the device from the wafer (skin barrier) during use. It was determined that the coupling on the device required design improvements.

Study #5

The device coupling system was re-designed to improve security and address the issues identified in the previous study. The study was conducted and concluded with no noted safety issues.

Study #6

No changes were made to the device design from the previous study in this Phase II study.

The extended portion of this trial was conducted to evaluate a change in the assembly process for the airbag. Of note during this trial were the reports of gastrointestinal adverse events such as diarrhea, nausea and vomiting with the use of the Vitala™/PAMS device. Another area of notable findings was the reports of stoma changes during wear of the PAMS device. Two subjects reported small spots on the stomas, one light gray and one as a dark area. These events resolved when the device was removed. Two other subjects reported a total of 3 small stoma cuts which also resolved when the device was removed. These events, GI and stoma, warranted further investigation into the causal relationship of the Vitala™ device to these types of safety adverse events. At this point ConvaTec assembled a team to review the relevant clinical data to determine what design issues, if any, needed to be addressed.

Study #7

The design of the device was modified to address the findings of the previous clinical trial and to facilitate use. The pump was eliminated. A soft open cell foam insert was placed in the airbag to make it self-inflating. The foam insert also provided a low-level baseline contact pressure between the airbag and stoma of 19-25 mmHg. A valve was built into the airbag subassembly to control the flow of air into and out of the airbag. This allowed the airbag to respond to short-term challenges to the airbag seal (e.g., due to coughing or sneezing), while preventing high contact pressure between the airbag and stoma for more than a few minutes at a time. Other features to facilitate application and ease of use were added.

The next and final study was a Phase II which was conducted to evaluate the safety and efficacy of the Vitala™ device when used for a maximum of eight hours per day. Based on the safety profile of this study the Vitala™ device was found to be safe to use.

Adverse events considered related to the use of the Vitala™ device were reported for 3 of the 25 subjects who used the device. No subject discontinued from the study due to an adverse event. Four subjects experienced serious AEs, one during the SUR-FIT® Natura® Durahesive® stage (chest pain) and three during the Vitala™ stage (anemia, bone fracture and seizure): none were considered related to study treatment. Section 20 provides complete study information.

The Vitala™ device is effective for colostomates based on the efficacy profile of this study. Section 20 provides complete study information.

Microbiology studies were conducted on all subjects. The data from all subjects in the study indicated no detection of the toxins, nor any aberrant aspects of the microbial flora in either normal circumstance, or with GI events (information is included in Section 20).

Vascularity of the stoma was studied in approximately half of the subjects: The data from all subjects in the vascular portion of the study indicated that the Vitala™ device did not cause major ischemic change on stoma in terms of mean oxygen saturation (SO_2) values compared to the Usual product (information is included in Section 20).

Results of the above studies determined the Vitala™ device was safe and effective when used for a maximum of eight hours.

Post Clinical Design Changes

Several "non-significant" post-trial design changes have been made to the packaging of the device, the airbag film color, and other minor changes to aid in application and removal of the device, and general improvement of the device.

The 45mm device was modified to reduce the effort required to apply it to the skin barrier (wafer), making it equivalent to the effort required to apply a 57mm Vitala™ device. This change was made to address non-serious adverse events in the previous clinical trial related to high application force for 45mm devices.

Devices made with the post clinical design changes are expected to perform equally well or better than the devices tested in the last clinical trial, while making the overall use of the device easier for the user. Laboratory testing has confirmed that the new device will perform in a similar manner.

Overall Conclusions

There are no significant differences in the intended use between the Vitala™ Continence Control Device and the Conseal Colostomy Continence System. The Vitala™ device is non-invasive to the stoma, and has demonstrated safety and efficacy through use in clinical trials, microbiology studies, and vascularity testing of the stoma. The device has the same intended action as the predicate device, which has an invasive absorbent membrane (plug) component that expands to create a seal in the stoma when in contact with effluent to create continence control.

Based on the evidence provided, we propose that Vitala™ Continence Control Device can be used safely and effectively for individuals with end colostomies to prevent the release of stool from an end colostomy, for a wear time of up to eight hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

APR - 2 2010

Ms. Patricia Kearins
Manager, Regulatory Affairs
ConvaTec
200 Headquarters Park Drive
SKILLMAN NJ 08558

Re: K083785
Trade/Device Name: Vitala™ Continence Control Device
Regulation Number: 21 CFR §876.5900
Regulation Name: Ostomy Pouch and Accessories
Regulatory Class: I
Product Code: EZQ
Dated: December 22, 2009
Received: December 23, 2009

Dear Ms. Kearins:

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.

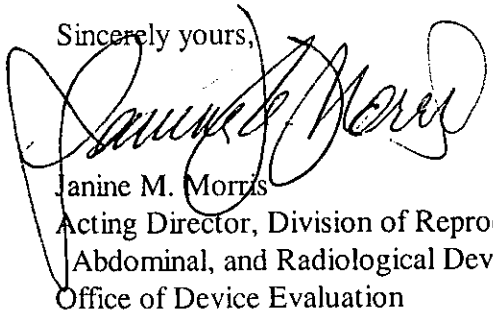
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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" (21CFR 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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Question 3

SECTION 4: Indications For Use Statement

510(k) Number (if known): K083785

Device Name: Vitala™ Continence Control Device

Indications for Use:

To prevent the release of stool from an end colostomy while allowing any gas that is present at the stoma to be deodorized and released. To be used only with a 1 ¾" (45 mm) or 2 ¼" (57 mm) ConvaTec Natura® skin barrier. Not intended for use with ConvaTec Moldable Technology™ skin barriers or convex products.

Prescription Use
(Part 21CFR 801.Subpart D)

OR

Over the Counter Use XX
(Part 21CFR 801 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 K083785