July 21, 2015

ConvaTec, Ltd.
Clare Williamson
Regulatory Affairs Documentation Compliance Manager
Unit 20, First Avenue, Deeside Industrial Park
Deeside, Flintshire CH5 2NU
UK

Re: K150350
Trade/Device Name: Flexi-Seal® Signal™ Fecal Management System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: June 18, 2015
Received: June 24, 2015

Dear Clare Williamson,

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 Industry and Consumer Education 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](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](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 Industry and Consumer Education 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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely yours,

Benjamin R. Fisher -S

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
510(k) Summary

**Subject Device:** Flexi-Seal® SIGNAL™ Fecal Management System

**Date Prepared:** February 06, 2015

**Applicant:** ConvaTec Ltd.
First Avenue
Deeside Industrial Park
Deeside
Flintshire CH5 2NU
UK

**Contact:** Clare Williamson
Regulatory Affairs Documentation Compliance Manager
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Fax: +44 (0)1244 584311
Email: clare.williamson@convatec.com

**Device Trade Name:** Flexi-Seal® SIGNAL™ Fecal Management System

**Common Name:** Fecal Management System

**Classification Name:** Gastrointestinal Tube and Accessories (21 CFR §876.5980, Product Code: KNT)

**Device Class:** Class II

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**Predicate Device:**

**Device Trade Name:** Flexi-Seal® SIGNAL™ Fecal Management System - ConvaTec Inc.

**Common Name:** Fecal Management System

**Classification Name:** Gastrointestinal Tube and Accessories (21 CFR §876.5980, Product Code: KNT)

**Device Class:** Class II

**510(k) Substantial Equivalence:** K112342 - determined substantially equivalent on April 26, 2012

**Device Description:**
The Flexi-Seal® SIGNAL™ Fecal Management System is comprised of a soft catheter tube assembly, a Luer-lock syringe, a collection bag with cap and a cinch clamp to pinch off flow in the catheter when required for medication retention or to stop waste flow. The components are contained in a rigid thermoformed plastic clamshell.

The catheter main drain tube is fabricated from collapsible silicone rubber with the addition of an odor adsorber, which is added in order to help contain the fecal odor which often permeates through the wall of the catheter.

The drain tube has a low-pressure silicone retention balloon at the distal end and a connector for attaching a collection bag (provided with the device and also available separately) at the proximal end. There is a recess (pocket) under the balloon for the clinician’s finger, which allows the device to be positioned digitally.

Two ports are attached to the side of the catheter. One port is used to inflate the retention balloon with water or saline after the device has been inserted into the patient’s rectum. This port also provides a visual and tactile signal of when the low pressure retention balloon is filled to its optimal volume. The other port is used to flush the device if needed and administer medication if prescribed.

An additional sampling port is located on the side of the catheter, which allows access to clinicians for stool sample collection.

A syringe (provided with the device) is used to fill and evacuate the retention balloon for insertion and removal.

The device, collection bag and syringe are intended for single use, are provided non-sterile and contain no components made with animal products, natural rubber latex or DEHP.

This Traditional 510(k) concerns modifications which do not alter the indications for use of the predicate device, the Flexi-Seal® SIGNAL™ Fecal Management System (ref. K112342).

**Intended use:**

The Flexi-Seal® SIGNAL™ Fecal Management System is an indwelling fecal management catheter intended for use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications. The device is not intended for use on pediatric patients.

**Summary of Technological Characteristics:**

The Flexi-Seal® SIGNAL™ Fecal Management System has the same intended use and indications for use as the predicate device, however the tubing now incorporates odor adsorbing properties. The adsorber reduces the odor which often permeates through the wall of the catheter. These unpleasant odors during catheter use can cause major discomfort to the patients, caregivers and visitors. Therefore, the reduction of odor is advantageous to overall patient wellbeing.

The device specifications are essentially identical to those of the predicate device, although minor adjustments have been made to the catheter tubing to
ensure that the material softness remains. Catheter tube diameter, catheter tube hardness, catheter tube tensile strength, and balloon-catheter bonding were evaluated via bench testing and are substantially equivalent to the predicate device. There are no differences in operation between the Flexi-Seal® SIGNAL™ Fecal Management System and the predicate device.

**Summary of Performance (Non-Clinical Testing) Data:**

Non-clinical testing of the subject device for functional and structural parameters has been performed. In this testing, the device’s performance has been found to be substantially equivalent to the aforementioned predicate device both functionally and structurally (material strength, catheter size, balloon size, etc.). The device has also been evaluated for biocompatibility in accordance with the US Food and Drug Administration’s guidance entitled *Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing’*, issued May 1, 1995, and has been found safe in such respect for its intended use.

In conclusion, the subject device has been demonstrated as safe and effective and substantially equivalent to the predicate device.
Summary of Technological Characteristics

The following table summarises the technological characteristics of the subject and predicate devices (ref. K112342, determined substantially equivalent on April 26, 2012) and outlines the product characteristics and specifications which form the basis of the substantial equivalence discussion.

The intended use, technological characteristics and principles of operation of the Flexi-Seal® SIGNAL™ Fecal Management System remains the same as those of the predicate device.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Flexi-Seal® SIGNAL™ Fecal Management System</td>
<td>Flexi-Seal® SIGNAL™ Fecal Management System</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(K112342)</td>
<td></td>
</tr>
<tr>
<td>FDA Product Code</td>
<td>KNT</td>
<td>KNT</td>
<td>Both devices are the same</td>
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<tr>
<td>FDA Classification Regulation</td>
<td>21 CFR 876.5980</td>
<td>21 CFR 876.5980</td>
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<tr>
<td>Regulatory Class</td>
<td>Class II</td>
<td>Class II</td>
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<tr>
<td>Intended Use</td>
<td>To manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications</td>
<td>To manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Functional configuration</td>
<td>Collapsible catheter with distal end secured in the rectum and proximal end connected to a collection bag</td>
<td>Collapsible catheter with distal end secured in the rectum and proximal end connected to a collection bag</td>
<td>Both devices are the same</td>
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<tr>
<td>Retention feature</td>
<td>Soft annular balloon</td>
<td>Soft annular balloon</td>
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</tr>
<tr>
<td>Balloon material</td>
<td>Silicone rubber</td>
<td>Silicone rubber</td>
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<tr>
<td>Inflation management</td>
<td>Sealed water filled balloon</td>
<td>Sealed water filled balloon</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Retention balloon inflation material</td>
<td>Water/saline (45ml)</td>
<td>Water/saline (45ml)</td>
<td>Both devices are the same</td>
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<tr>
<td>Catheter tube length</td>
<td>1,550mm - 1,670mm</td>
<td>1,550mm - 1,670mm</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Length of sphincter section</td>
<td>&gt;10cm</td>
<td>&gt;10cm</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Parameter</td>
<td>Subject Device</td>
<td>Predicate</td>
<td>Comparison</td>
</tr>
<tr>
<td>-----------------------------------</td>
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<tr>
<td></td>
<td>Flexi-Seal® SIGNAL™ Fecal Management System</td>
<td>Flexi-Seal® SIGNAL™ Fecal Management System (K112342)</td>
<td></td>
</tr>
<tr>
<td>Drain channel</td>
<td>Large main drain tube</td>
<td>Large main drain tube</td>
<td>Both devices are the same</td>
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<tr>
<td>Inflation and irrigation port connections</td>
<td>Luer</td>
<td>Luer</td>
<td>Both devices are the same</td>
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<tr>
<td>Inflation lumen diameter</td>
<td>Two lumens at 1.45 mm</td>
<td>Two lumens at 1.45 mm</td>
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<td>Inflation lines</td>
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<td>Irrigation lines</td>
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<tr>
<td>Sampling port</td>
<td>Closable snap seal for catheter syringe access</td>
<td>Closable snap seal for catheter syringe access</td>
<td>Both devices are the same</td>
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<tr>
<td>Collection bag configuration</td>
<td>Disposable with gas filter</td>
<td>Disposable with gas filter</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Collection bag size</td>
<td>1 litre disposable</td>
<td>1 litre disposable</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Method of bed connection</td>
<td>Hanging strap on bag connector</td>
<td>Hanging strap on bag connector</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Accessory components</td>
<td>Syringe and cinch clamp</td>
<td>Syringe and cinch clamp</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Flow stop mechanism</td>
<td>External cinch clamp</td>
<td>External cinch clamp</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Sterility status (how provided)</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
<td>Both devices are the same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Thermoformed plastic clamshell</td>
<td>Thermoformed plastic clamshell</td>
<td>Both devices are the same</td>
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</tbody>
</table>