APR 26 2012

510(K) SUMMARY

Subject Device:	**Flexi-Seal® SIGNAL™ Fecal Management System**
Date Prepared:	**4/24/2012**
Applicant:	ConvaTec Inc. 200 Headquarters Park Drive Skillman, New Jersey 08558
Contact:	**Katrina Fiedler** Associate Director, US Regulatory Affairs ConvaTec Inc. Tel: 908-904-2541 Fax: 908-904-2235
Device Trade Name:	Flexi-Seal® SIGNAL™ Fecal Management System
Classification Name:	Gastrointestinal Tube and Accessories (ref. 21 CFR 876.5980; Product Code KNT)
Device Class:	Class II

Predicate Devices:

Trade Name:	Flexi-Seal® Fecal Management System – ConvaTec Inc.
Classification Name:	Gastrointestinal Tube and Accessories (ref. 21 CFR 876.5980; Product Code KNT)
Device Class:	Class II
510(k) Substantial Equivalence:	K032734 – determined substantially equivalent on April 8, 2004

Trade Name:	Indwelling Fecal Management System – Bowel Management Systems, LLC
Classification Name:	Gastrointestinal Tube and Accessories (ref. 21 CFR 876.5980; Product Code KNT)
Device Class:	Class II
510(k) Substantial Equivalence:	K012113 – determined substantially equivalent on May 3, 2002

Device Description:

The Flexi-Seal® SIGNAL™ Fecal Management System is comprised of a soft catheter tube assembly, a Luer Syringe, a collection bag with filter and a cinch clamp to pinch off flow in the catheter when required for medication retention. The components are contained in a snap closed tray.

The catheter main drain tube is fabricated from collapsible silicone rubber. The drain tube has a low-pressure polyurethane or silicone retention balloon at the distal end and a connector for attaching a collection bag (provided with the device and separately) at the proximal end. There is a recess under the balloon for the clinician's finger allowing 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.

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 us, are provided non-sterile, and have no components made with animal products, natural rubber latex or DEHP.

This 510(k) concerns modifications to the indications for use, materials and design featured with the predecessor device, the ConvaTec Fecal Management System (ref. K032734).

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.

Summary of Technological Characteristics:

The Flexi-Seal® SIGNAL™ Fecal Management System has the same intended use and indications for use but with the addition of the access to administer medication. The approximate geometry of the new device is the same as the predicate devices. The materials and construction are the same as the predicate devices with the exception of a polyurethane balloon version additional to the original silicone retention balloon. This just provides an alternate substitute material for the retention balloon. The only differences in operation between the Flexi-Seal® SIGNAL™ Fecal Management System and the predicate devices are the use of a port to gather samples rather than the bag coupling and the use of an external separate cinch clamp to retard waste flow when desired. One of the predicate devices Indwelling Fecal Management System (ref. K012113) uses an internal inflatable balloon to block flow and has a sampling port.

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 devices 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 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Katrina Fiedler
Associate Director, US Regulatory Affairs
ConvaTec Inc.
200 Headquarters Park Drive
SKILLMAN NJ 08558

APR 26 2012

Re: K112342
Trade/Device Name: Flexi-Seal® SIGNAL™ Fecal Management System (FMS)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 27, 2012
Received: March 29, 2012

Dear Ms. Fiedler:

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,

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

510(K) Number (if known): ~~*Not yet assigned*~~ K112342

Device Name: **Flexi-Seal® SIGNAL™ Fecal Management System (FMS)**

Indication for Use:

For use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications.

Prescription Use **XX**
(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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112342