April 30, 2019

ConvaTec Limited
Jason Skramsted
Senior Regulatory Affairs Specialist
GDC, First Avenue, Deeside Industrial Park
Deeside, Flintshire CH5 2NU
United Kingdom

Re: K190114
Trade/Device Name: Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT, PIF
Dated: April 3, 2019
Received: April 4, 2019

Dear Jason Skramsted:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190114

Device Name

Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector)

Indications for Use *(Describe)*

The Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector) 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 intended for use in adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ConvaTec

Section 5
510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

1. **Applicant:** ConvaTec Limited
GDC, First Avenue
Deeside Industrial Park
Deeside
Flintshire, CH5 2NU
UK

Establishment Registration number 1000317571

Contact: Jason Skramsted
ConvaTec, Inc.
Senior Regulatory Affairs Specialist
Tel: 336-542-4753
Email: Jason.Skramsted@ConvaTec.com

Date Prepared: 23 January 2019

2. **Device Identification:**

Trade Name:	Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector)
Common Name:	Fecal Management System
Regulation Number:	21 CFR §876.5980
Classification Panel:	Gastroenterology and Urology
Classification Name:	Gastrointestinal tube and accessories
Regulatory Class:	II
Product Classification Code:	KNT, PIF

3. **Predicate Devices:**

Predicate Manufacturer:	ConvaTec Limited
Predicate Trade Name:	Flexi-Seal™ PROTECT Fecal Management System
Predicate 510 (k):	K162906

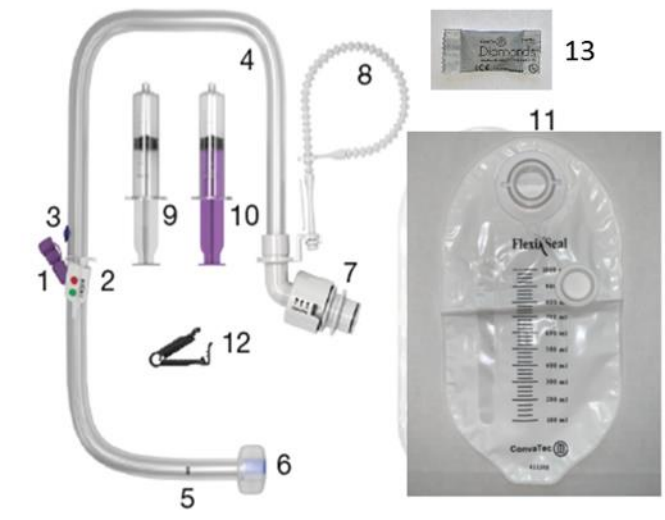
4. Device Description

The subject device, Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector), has the same intended use as the predicate device (K162906). Both devices include a low-profile retention balloon, a finger pocket to allow for easy balloon insertion, a green dome to indicate the optimal fill status of the retention balloon, a red dome to indicate the over inflation status, and the ability to administer medication through the use of a cinch clamp. In addition, the subject device incorporates new features, including:

(1) add a self-closing ENFit port for irrigation/medication and provide an ENFit syringe in the kit,
(2) add a sub-assembled self-closing quick connector to the catheter end, and
(3) add a matching bag connector in the collection bag with an option of incorporating Diamonds™ gelling and odor control sachet (4 sachets per kit) to solidify and deodorize the fecal contents in the collection bag.

The subject device is comprised of the following components (in a clamshell pack with label card, IFU and 5 date labels) see Figure 1.

Figure 1: Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector)



1 Catheter Irrigation and Medication Port
2 Balloon Inflation Port with 2-Dome Fill Indicator and Cap
3 Sampling Port
4 Catheter
5 Position Indicator Line
6 Low-Pressure Retention Balloon with Finger Pocket
7 Self-Closing Connector
8 Hanging Strap
9 Luer-Lock Syringe
10 ENFit Syringe
11 Collection Bag
12 Cinch Clamp
13 Diamonds™ gelling and odor control sachet

Figure 2 represents an overview of the predicate device:

Figure 2: Flexi-Seal™ PROTECT Fecal Management System

5. Intended Use

The Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector) 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 intended for use in adult patients.

6. Performance Testing – Bench

There are no differences in the intended use or performance of the subject device and the predicate device. The device specifications are identical to those of the predicate device K162906, except for the new features described above. In addition to biocompatibility and stability tests, the following performance tests of the subject device were performed (results are detailed in Section 18 of this Submission):

(1) Joint strength of new ENFit™ connector to the catheter
(2) Joint strength of ENFit™ connector to the irrigation port housing
(3) Drug efficacy in ENFit™ connector
(4) Water leakage test of the ENFit™ connector
(5) Water leakage test of the self-closing catheter connector (both during use or when the bag is removed)

Based on non-clinical testing of the subject device for functional and structural parameters, the modifications in the subject device do not affect the safety and effectiveness. Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector) described in this submission is, in our opinion, substantially equivalent to the predicate device, Flexi-Seal™ PROTECT Fecal Management System (K162906).

7. Comparison of technological characteristic with the predicate device

It has been demonstrated through comparison of design features and performance testing, that the proposed device and its predicate have been found to be substantially equivalent.

The intended use, technological characteristics and principles of operation of the subject device remain the same as those of the predicate device.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-life Testing
See Section 14

Biocompatibility Testing
See Section 15

Electrical safety and electromagnetic compatibility (EMC)
Not Applicable

Software Verification and Validation Testing
Not Applicable

Mechanical and acoustic Testing
Not Applicable

Animal Study
Animal performance testing was not required to demonstrate the safety and effectiveness of the proposed device.

Clinical Studies
Clinical testing was not required to demonstrate the safety and effectiveness of the proposed device. Instead, substantial equivalence is based upon benchtop performance testing.

Table 1: Comparison of Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector) vs Flexi-Seal™ PROTECT Fecal Management System (K162906), Bard™ DigniShield™ Stool Management System ENFit™ and Bard™ DigniShield™ Stool Management System

Name	Subject Device: Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector)	Predicate Device: Flexi-Seal™ PROTECT Fecal Management System (K162906)	Bard™ DigniShield™ Stool Management System ENFit™	Bard™ DigniShield™ Stool Management System (K133251)
Intended Use	Fecal Management	Fecal Management	Fecal Management	Fecal Management
Indications	The Flexi-Seal™ PROTECT PLUS Fecal Management System is an indwelling fecal management catheter intended for use to manage fecal incontinence through the collection of liquid or semi-liquid stool and to provide access to administer medications.	The Flexi-Seal™ PROTECT Fecal Management System is an indwelling fecal management catheter intended for use to manage fecal incontinence through the collection of liquid or semi-liquid stool and to provide access to administer medications.	Bard DigniShield™ Stool Management System is intended for fecal management by diverting and collecting liquid and semi-liquid stool to minimize skin contact in bedridden patients and to provide access for the administration of medications. Adult Use Only.	Bard DigniShield™ Stool Management System is intended for fecal management by diverting and collecting liquid and semi-liquid stool to minimize skin contact in bedridden patients and to provide access for the administration of medications. Adult Use Only.
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Max Usage of Device	29 days	29 days	29 days	29 days
Balloon fill volume per IFU	35 - 45 ml based on fill indicator	35 - 45 ml based on fill indicator	45 ml	45 ml
Optimal balloon fill volume to be indicated by a visual fill indicator	Yes	Yes	No	No
Over-inflation indicator	Yes	Yes	No	No

Odor Barrier Catheter	Yes	Yes	Yes	Yes
Catheter Material	Silicone with Zeolite	Silicone with Zeolite	Thermoplastic Elastomer and Silicone	Thermoplastic Elastomer and Silicone
Medication Delivery	Yes	Yes	Yes	Yes
ENFit™ Port for irrigation and medication (ISO 80369-3)	Yes	No (Luer)	Yes	No (Luer)
Self-Closing ENFit™ Port	Yes	No	No	No
ENFit™ Syringe in the kit	Yes	No	No	No
Self-Closing Catheter Connector	Yes	No	Yes	Yes
Collection Bag	Close with a cap (not self-closing)	Close with a cap (not self-closing)	Close with a cap (not self-closing)	Close with a cap (not self-closing)
Odor Control Sachet or Spray	Diamonds™ Gelling and odor control sachets for collection bag	No	Odor eliminator spray	Odor eliminator spray

Note: Bard DigniShield™ Stool Management System ENFit™ is used as a comparison device for the ENFit and self-closing catheter connector only

ENFit™ is a trademark of Global Enteral Device Supplier Association (GEDSA)

Flexi-Seal™, Signal™ , Diamonds™ – Trademark of ConvaTec Inc., NJ

Bard™ and DigniShield™– Trademark of CR Bard, Inc. Covington,

9. Conclusion

The modifications made to the existing device do not alter its intended use, change fundamental performance, or introduce new questions of safety and efficacy when compared with the predicate device. This comparison demonstrates that Flexi-Seal™ PROTECT PLUS Fecal Management System (with ENFit™ connector) is substantially equivalent to ConvaTec's previously cleared Flexi-Seal™ PROTECT Fecal Management System (K162906).