DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 7, 2017

ConvaTec
Karen Howes
Regulatory Affairs Manager
GDC, First Avenue, Deeside Industrial Park
Deeside, Flintshire CH5 2NU
United Kingdom

Re: K162906
Trade/Device Name: Flexi-Seal® PROTECT™ Fecal Management System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: February 2, 2017
Received: February 6, 2017

Dear Karen Howes:

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. 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 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.

Sincerely,

Joyce M. Whang -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown K162906

Device Name

Flexi-Seal® PROTECT ™ Fecal Management System

Indications for Use *(Describe)*

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 to semi-liquid stool and to provide access to administer medications. The device is not intended for use on pediatric 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.

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ConvaTec

Section 5
510(k) Summary

Applicant: ConvaTec Limited.

Applicant Address: GDC, First Avenue
Deeside Industrial Park
Deeside
Flintshire CH5 2NU
UK
The Establishment Registration number is 1000317571

Contact: Karen Howes
Regulatory Affairs Manager
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UK
Tel: +44(0) 1244832195

Date Prepared: 1 December 2016

Device Identification:

Trade Name: Flexi-Seal® PROTECT™ Fecal Management System
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 Code: KNT

Predicate Devices:
510(K) number: K150350 Flexi-Seal® SIGNAL™ Fecal Management System

Device Description

The new device is called Flexi-Seal® PROTECT™ Fecal Management System which is an upgrade to the predicate device K150350, Flexi-Seal® Signal™ Fecal Management System (also known as Flexi-Seal® Signal™ Fecal Management System with Odor Barrier), launched in October 2015. The new device uses the same design and components except

(1) the change from the 1-dome fill indicator to a new 2-dome fill indicator to provide visual cue by using
    (a) a green color dome to indicate an optimal fill status of retention balloon which is similar to the existing fill indicator except the color, and
    (b) a red color dome to indicate the over inflation status of retention balloon,

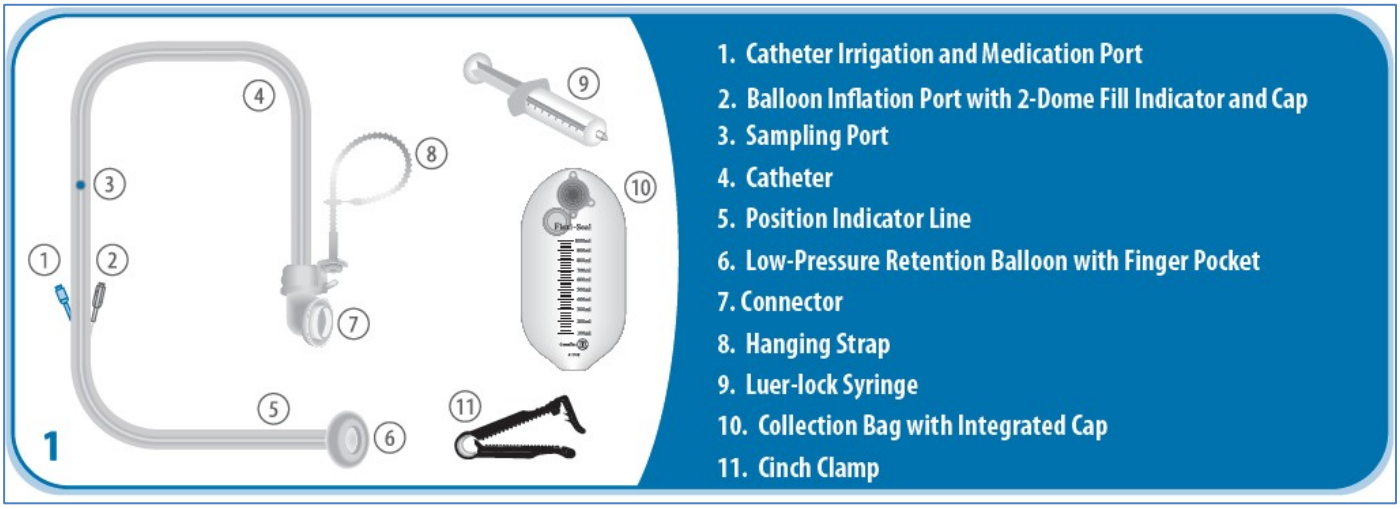
(2) adding a white cap that can close off the inflation port,

(3) adding a dark blue color in the sample port, and

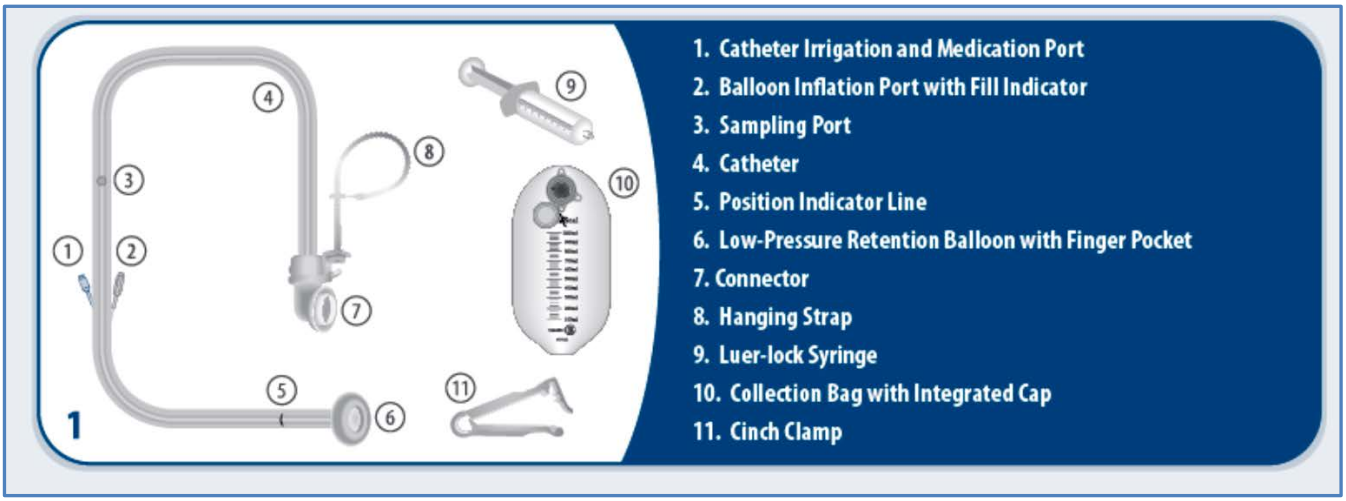
(4) Privacy bag (one bag instead of 3).

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

New device Flexi-Seal® PROTECT™ Fecal Management System



Predicate device: Flexi-Seal® SIGNAL™ Fecal Management System



Intended Use

The Flexi-Seal PROTECT FMS 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**.**

Performance Testing – Bench

There are no differences in the intended use or performance of the subject and the predicate device. Non clinical testing has been conducted on the predicate and subject devices. The list of non-clinical testing for which the results are detailed in Sec. 18 includes:

1. Fill indicator testing:
    a. Fill indication for optimal inflation volume of retention balloon
    b. Fill Indictor for overfilling status of retention balloon
    c. Fill Indicator joint strength to catheter
    d. Luer valve joint strength to Inflation Port
    e. Green ink adhesion
    f. Red ink adhesion
2. Inflation port cap testing:
    a. Cap joint strength to the fill indicator
    b. Cap removal force
    c. Cap repeated removal 5 times
3. Sampling port testing:
    a. Sampling port seal against air
    b. Sampling port seal against water
4. Privacy bag testing:

a. Width of clear window at 10 - 25 mm
b. Graduation at 500 ml is within ± 15%
c. Graduation at 1000 ml is within ± 15%
d. Pouch has 1 Liter capacity
e. Ink Adhesion

5. Journey hazard testing:
    a. Journey hazard testing
    b. Post-JHT Product Release Testing – Visual, Color, and Cap
    c. Post-JHT Product Release Testing - Fill indication for optimal inflation volume of retention balloon
    d. Post-JHT Product Release Testing - Fill Indictor for overfilling status of retention balloon

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 of the predicate device. Flexi-Seal® PROTECT™ Fecal Management System described in this submission is, in our opinion, substantially equivalent to the predicate device, Flexi-Seal® SIGNAL™ Fecal Management System per K150350.

Substantial Equivalence Conclusion

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; see following pages.

Substantial Equivalence Discussion

The following table compares the similarities and differences between the subject device: Flexi-Seal® PROTECT™ Fecal Management System and the predicate device: Flexi-Seal® SIGNAL™ Fecal Management System (ref; K150350) 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 fecal management system remains the same as those of the predicate device.

Parameter	Subject Device Flexi-Seal® PROTECT™ Fecal Management System	Predicate Flexi-Seal® SIGNAL™ Fecal Management System (K150350)	Comparison	
			Similarities	Differences
FDA Product Code	KNT	KNT	Both devices are the same	None
FDA Classification Regulation	21 CFR 876.5980	21 CFR 876.5980	Both devices are the same	None
Regulatory Class	Class II	Class II	Both devices are the same	None
Intended Use	To manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications	To manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications	Both devices are the same	None
Functional configuration	Collapsible catheter with distal end secured in the rectum and proximal end connected to a collection bag	Collapsible catheter with distal end secured in the rectum and proximal end connected to a collection bag	Both devices are the same	None
Retention feature	Soft annular balloon	Soft annular balloon	Both devices are the same	None
Balloon material	Silicone rubber	Silicone rubber	Both devices are the same	None
Inflation management	Sealed water filled balloon	Sealed water filled balloon	Both devices are the same	None
Retention balloon	Water/saline (45ml)	Water/saline (45ml)	Both devices are the	None

inflation material			same	
Retention balloon inflated diameter	56.82mm	56.82mm	Both devices are the same	None
Retention balloon inflated height	25.96mm	25.96mm	Both devices are the same	None
Catheter tube material	Silicone rubber plus 3% zeolite, by weight	Silicone rubber plus 3% zeolite, by weight	Both devices are the same	None
Catheter tube surface roughness	<15µm	<15µm	Both devices are the same	None
Fill indication for optimal inflation volume of retention balloon	Green dome inflated at 35 – 45 ml	White dome inflated at 35 – 45 ml	Except color, both devices provided the same visual indication for optimal balloon inflation volume. The dimension of the fill indicator is similar.	Color
Fill Indictor for overfilling status of retention balloon	Red dome inflated beyond 45 ml and above	None	A new feature in the subject device using a similar fill indicator design	A new feature in the subject device
Cap for inflation port	A removable silicone cap to close off the inflation port with sufficient removal force and joint strength	None	A new feature in the subject device to differentiate the inflation port from the irrigation port	A new feature in the subject device
Catheter tube hardness	Shore A 38.5 - 51	Shore A 38.5 - 51	Both devices are the same	None
Catheter tube wall thickness	0.40 - 0.65mm	0.40 - 0.65mm	Both devices are the same	None
Catheter tube tensile strength	245N	245N	Both devices are the same	None
Balloon-to-tube bonding strength	25.4N	25.4N	Both devices are the same	None

Catheter tube length	1,550mm - 1,670mm	1,550mm - 1,670mm	Both devices are the same	None
Length of sphincter section	>10cm	>10cm	Both devices are the same	None
Drain channel	Large main drain tube	Large main drain tube	Both devices are the same	None
Inflation and irrigation port connections	Luer	Luer	Both devices are the same	None
Inflation lumen diameter	Two lumens at 1.45 mm	Two lumens at 1.45 mm	Both devices are the same	None
Inflation lines	2	2	Both devices are the same	None
Irrigation lines	1	1	Both devices are the same	None
Irrigation lumen size	8mm x 1.6mm (collapsible)	8mm x 1.6mm (collapsible)	Both devices are the same	None
Sampling port	Closable snap seal for catheter syringe access - dark blue color	Closable snap seal for catheter syringe access – natural color	Except color, both devices provided the same seal against water and air.	Color
Waste lumen diameter collapsed	10mm	10mm	Both devices are the same	None
Collection bag configuration	Disposable with gas filter	Disposable with gas filter	Both devices use the same filter, flange, and film panels in the collection bag.	One bag in the subject device vs. three bags in the predicate device
Collection bag size	1 litre disposable	1 litre disposable	Both devices are the same	None
Collection bag material	Ethyl vinyl acetate	Ethyl vinyl acetate	Both devices are the same	None

Collection bag - front panel color	White with a clear window	Clear	Except color in the front panel, both bags perform the same	Color
Method of bed connection	Hanging strap on bag connector	Hanging strap on bag connector	Both devices are the same	None
Accessory components	Syringe and cinch clamp	Syringe and cinch clamp	Both devices are the same	None
Flow stop mechanism	External cinch clamp	External cinch clamp	Both devices are the same	None
Sterility status (how provided)	Non-sterile	Non-sterile	Both devices are the same	None
Packaging	Thermoformed plastic clamshell PETG (POLYETHYLENE TEREPHTHALATE GLYCOL-MODIFIED) or APET (AMORPHOUS POLYETHYLENE TEREPHTHALATE), both sides coated with 2% silicone.	Thermoformed plastic clamshell PETG (POLYETHYLENE TEREPHTHALATE GLYCOL-MODIFIED) or APET (AMORPHOUS POLYETHYLENE TEREPHTHALATE), both sides coated with 2% silicone.	Both devices use the same packaging material	None