March 28, 2025

Convatec
Michael Chitiyo
Regulatory Affairs Specalist
First Avenue, Deeside Industrial Estate
Deeside
Flintshire, CH5 2NU
United Kingdom

Re: K243228
Trade/Device Name: Flexi-Seal AIR (with ENFit Connector)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT, PIF
Dated: October 24, 2024
Received: February 28, 2025

Dear Michael Chitiyo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anthony Lee -S

Anthony C. Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243228

Device Name

Flexi-Seal AIR (with ENFit™ Connector)

Indications for Use *(Describe)*

Flexi-Seal AIR™ (with ENFit™ Connector) is an indwelling fecal management catheter intended 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Date: 24/March/2025

510(k) Summary

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

1. Applicant:

ConvaTec Limited,
GDC Building First
Avenue
Deeside Flintshire,
GB CH5 2NU
Establishment Registration number 3008806809

Contact: Courtney Smith
ConvaTec, Inc.
Senior Director Regulatory Affairs Ostomy Care & Continence Care
Tel: 239-7762947
Email: courtney.smith@convatec.com

2. Device Identification:

Trade Name	Flexi-Seal AIR (with ENFit Connector)
Common Name	Fecal Management System
Regulation Number	21 CFR §876.5980
Classification Name	Gastrointestinal tube and accessories
Regulatory Class	II
Product Classification Code	KNT
Device Description	The Flexi-Seal Air™ (supplied non-sterile) is comprised of a low pressure foam-filled 100% silicone rectal retention balloon fixed to the distal end of a soft collapsible silicone catheter tube with a labelled white inflation port and an auto Inflate valve, Luer lock inflation syringe, an ENFit connector for irrigation/medication port with an ENFit compatible syringe, cinch clamp, date formatted labels, a sub-assembled self-closing quick connector to the catheter end, a matching collection bag, and "Diamonds" gelling and odor control sachets (4 sachets per kit). The components are contained in a rigid thermoformed plastic clamshell. The following is a list of design changes in the subject device, Flexi-Seal Air™ versus the primary predicate device, Flexi-Seal® PROTECT Plus Fecal Management System ref K190114. (1) A new foam filled retention balloon which is similar to the existing balloon in function and use. A single pilot balloon indicator is used to assess if the balloon is fully deflated or

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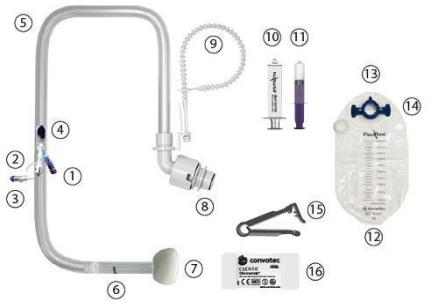
	approximately filled. Air is used instead of water for balloon inflation. (2) Addition of an auto-valve to automatically inflate the balloon, self-regulate the balloon pressure to 0 mm Hg, and release of excessive balloon pressure to prevent balloon over-inflation during bowl/patient movement. (3) Addition of an odor barrier outer polyurethane tube to the external of the current silicone tube using the tube-in-tube design except the first 10cm of the balloon end which is still a 100% silicone tube without polyurethane. (4) A revised blue color silicone cover with fingertip grips and a taller key at the bag flange to mitigate use errors in coupling the bag upside down and trapping the bag film and minor print edits in the catheter connector. These print modifications include a blue arrow (catheter side) that corresponds with the taller blue key (bag side) and a red 'no-entry' symbol to show when the connector is in the upside-down orientation.  1 Catheter Irrigation and Medication Port – ENFit™ 2 Balloon Inflation/Deflation Port with Pilot Balloon Indicator 3 Auto Inflate Valve 4 Sampling Port 5 Catheter (including Tube-in-Tube after Black Mark) 6 Position Indicator Line 7 Low-Pressure Retention Balloon with Finger Pocket 8 Self-Closing Connector 9 Hanging Strap 10 Luer-Lock Syringe 11 ENFit™ Syringe 12 Collection Bag 13 Blue Key 14 Fingertip Grips 15 Cinch Clamp 16 4 ConvaTec Diamonds™ gelling and odor control sachets
Indications for Use	Flexi-Seal AIR™ (with ENFit™ Connector) is an indwelling fecal management catheter intended 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.
Performance Data	Performance testing for Flexi-Seal Air™ was conducted for functional and structural parameters. In this testing, the device's performance has been found to be substantially equivalent to the predicate device both functionally and structurally (balloon, auto inflate valve, joint strength, mechanical properties, odor barrier, 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 10993-1:2018, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process'*, issued September 8, 2023, 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 K190114.

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Technological Comparison	Fecal management system is the intended technological principle for both the subject and predicate devices. At a high level Flexi-Seal Air™ and the primary predicate Flexi-Seal Protect Plus are based on the following same technological elements: - Indications for use - Low profile retention balloon - A finger pocket to allow for easy balloon insertion. - A silicone catheter - A pilot balloon at the inflation/deflation port to indicate the fill status of the retention balloon. - A quick connector that self-closes when bag is connected - Ability to administer the medication through the use of a cinch clamp. The following is a list of design changes in the subject device, Flexi-Seal Air™ versus the predicate device, Flexi-Seal® PROTECT Plus Fecal Management System ref K190114: - A new foam filled retention balloon, which is inflated with air. - Addition of an auto-valve to automatically inflate the balloon. - Addition of an odor barrier outer polyurethane tube - A revised blue color silicone cover with fingertip grips and a taller key at the bag flange and minor print edits in the catheter connector, a matching blue arrow that corresponds with the taller blue key and a red 'no-entry' symbol to show the connector is upside down.

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Device Comparison Table

Characteristic	Subject Device	Primary Predicate Device (K190114)
Name	Flexi-Seal Air™ ENFit	Flexi-Seal™ PROTECT Plus FMS
Intended Use	Fecal Management	Fecal Management
Indication for Use	Flexi-Seal Air™ 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.	The Flexi-Seal™ PROTECT Plus Fecal Management System is an indwelling fecal management catheter with odor barrier intended for use to manage fecal incontinence through the collection of liquid or semi-liquid stool and to provide access to administer medications. The device is not intended for use on pediatric patients.
Sterility	Non-Sterile	Non-Sterile
Max Usage of Device	29 days	29 days
Inflated Balloon Height for anchoring in rectum, mm	36	26
Retention Balloon Diameter for anchoring in rectum	60 - 61	57
Substance to inflate balloon	Air	Water/Saline
Balloon fill volume per IFU	NA – Auto inflate by connecting Auto inflate Valve	35 - 45 ml based on fill indicator
Balloon fill volume customized for each patient	Yes, automatically based on auto inflate valve	Yes, passively using fill indicator by HCP providers
Marked Balloon inflation visual indicator	Yes White dome shows inflation or deflation	Yes Green dome shows the optimal fill volume, and the red dome indicates over inflation.
Active Balloon Pressure Management	Yes - Balloon pressure less than 22 mm Hg	No – Only passive balloon pressure management using indicator
Automatic Excessive Pressure Relief	Yes	No
Means to mitigate balloon over-inflation risk	The device has an auto inflate valve with pressure relief to self-	Red dome signals over-inflation beyond 45 ml and above (or

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	regulate balloon pressure to less than 22 mm Hg	corresponding pressure above 50 - 70 mm Hg)
Balloon Insertion Depth Marking	Yes	Yes
Odor Barrier Catheter	Yes	Yes
Catheter Material	Tube-in-Tube (polyurethane outer tube and silicone inner tube)	Silicone with Zeolite
Medication Delivery	Yes	Yes
ENFit™ Port for irrigation and medication (ISO 80369-3)	Yes	Yes
Self-Closing ENFit™ Port	Yes	Yes
ENFit™ Syringe in the kit	Yes	Yes
Self-Closing Catheter Connector	Yes	Yes
Collection Bag	Close with a cap (not self-closing), 1 Liter	Close with a cap (not self-closing), 1 Liter
Odor Control Sachet or Spray	Diamonds™ Gelling and odor control sachets for collection bag	Diamonds™ Gelling and odor control sachets for collection bag

* ENFit™ is a trademark of Global Enteral Device Supplier Association (GEDSA).
Flexi-Seal™, Diamonds™ – Trademark of ConvaTec Inc., NJ

Overall Conclusions

There are no differences in the intended use or performance of the subject and the predicate device.

Based on non-clinical testing of the subject device for functional and structural parameters, the modifications in the subject device do not affect its safety and effectiveness. Flexi-Seal Air™ described in this submission is substantially equivalent to the predicate device of Flexi-Seal™ PROTECT Plus Fecal Management System K190114.