

**K190114 Flexi-Seal PROTECT PLUS Fecal Management System
(with ENFit Connector)**Apr 30, 2019
96 days to decisionK190114 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Jan 24, 2019
Decision date	Apr 30, 2019
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Convatec Limited
Location	Deeside, GB
Contact	Karen Howes
Website	https://www.convatec.com/
510(k) history	10 submissions · 9 cleared · 2016-2026

Convatec Limited is a global medical device manufacturer specializing in chronic disease management solutions. The company operates with a manufacturing facility in Deeside, United Kingdom, and serves patients and healthcare professionals worldwide through innovative product portfolios. Convatec has received FDA 510(k) clearances from total submissions since 2016. The company's cleared devices span Gastroenterology & Urology and General & Plastic Surgery categories, with a strong focus on intermittent urinary catheters, fecal management systems, and advanced wound care dr...

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