

K150350 Flexi-Seal Signal Fecal Management SystemJul 21, 2015
160 days to decisionK150350 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k150350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Feb 11, 2015
Decision date	Jul 21, 2015
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Convatec, Ltd.
Location	Deeside, GB
Contact	Clare Williamson
510(k) history	4 submissions · 2 cleared · 1997-2015

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