

K243228 Flexi-Seal AIR (with ENFit Connector)Mar 28, 2025
171 days to decisionK243228 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Oct 8, 2024
Decision date	Mar 28, 2025
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Convatec
Location	Skillman, NJ, US
Contact	Michael Chitiyo
510(k) history	7 submissions · 7 cleared · 2008-2025

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