

K250891 Cure Catheter Insertion Kit (K1)Jun 6, 2025
73 days to decisionK250891 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Mar 25, 2025
Decision date	Jun 6, 2025
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cure Catheter Insertion Kit (K2); Cure Catheter Insertion Kit (K2-90); Cure Catheter Insertion Kit (K3); Cure Hydrophilic Catheter Kit (HM12UK); Cure Hydrophilic Catheter Kit (HM14UK); Cure Hydrophilic Catheter Kit (HM16UK); Cure Pocket Catheter Kit (M14UK); Cure Catheter Closed System Kit (CS8); Cure Catheter Closed System Kit (CS10); Cure Catheter Closed System Kit (CS12); Cure Catheter Closed System Kit (CS14); Cure Catheter Closed System Kit (CS14C)

APPLICANT

Company	Convatec Limited
Location	Deeside, GB
Contact	Alexandra Hyde
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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