

K250699 Cure Twist Female 8 Catheter (T8)

Jul 1, 2025
116 days to decision

K250699 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250699/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Mar 7, 2025
Decision date	Jul 1, 2025
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cure Twist Female 10 Catheter (T10); Cure Twist Female 12 Catheter (T12); Cure Twist Female 14 Catheter (T14); Cure Twist Female 16 Catheter (T16); Cure Twist Female 8 Catheter Kit with supplies (T8K); Cure Twist Female 10 Catheter Kit with supplies (T10K); Cure Twist Female 12 Catheter Kit with supplies (T12K); Cure Twist Female 14 Catheter Kit with supplies (T14K); Cure Twist Female 16 Catheter Kit with supplies (T16K)

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k250699/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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