

K210250 SpeedCath Compact MaleApr 26, 2022
452 days to decisionK210250 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Jan 29, 2021
Decision date	Apr 26, 2022
Days to decision	452 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast
Location	Plymouth, MN, US
Contact	Delaney McDougal
Website	http://www.coloplast.com/
510(k) history	15 submissions · 14 cleared · 2018-2024

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