

**K222059 SpeediCath Flex Set**Sep 21, 2022  
70 days to decisionK222059 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k222059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Jul 13, 2022
Decision date	Sep 21, 2022
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coloplast</b>
Location	Plymouth, MN, US
Contact	Preeti Jain
Website	<a href="http://www.coloplast.com/">http://www.coloplast.com/</a>
510(k) history	15 submissions · 14 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222059/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 25, 2026