

**K100878 SELF CATH CATHETER**May 26, 2010  
57 days to decisionK100878 · Product code: **EZD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k100878/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Mar 30, 2010
Decision date	May 26, 2010
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coloplast Manufacturing Us, LLC</b>
Location	Minneapolis, MN, US
Contact	BRIAN SCHMIDT
510(k) history	4 submissions · 4 cleared · 2007-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100878/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 21, 2026