

**K233411 Folsil Silicone Catheter**Apr 15, 2024  
192 days to decisionK233411 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k233411/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Oct 6, 2023
Decision date	Apr 15, 2024
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coloplast Corp.</b>
Location	Marietta, GA, US
Contact	Brian Schmidt
510(k) history	54 submissions · 47 cleared · 1985-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kompass Regulatory Consulting</b>
Contact	Kristen Swanson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233411/> 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 14, 2026