

**K161770 Rusch Silicone Foley Catheter**May 5, 2017  
311 days to decisionK161770 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k161770/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jun 28, 2016
Decision date	May 5, 2017
Days to decision	311 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Teleflexmedical, Inc.</b>
Location	Jeffrey, NH, US
Contact	Lori Pfohl
510(k) history	64 submissions · 61 cleared · 1985-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161770/> 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 1, 2026