

**K252537 Rusch SoftSimplastic Foley Catheters**Jan 20, 2026  
161 days to decisionK252537 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252537/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Aug 12, 2025
Decision date	Jan 20, 2026
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Teleflex Medical Sdn. Bhd.</b>
Location	Kamunting, MY
Contact	Yuvaanesswary Nallappan
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252537/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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