

K162989 Rusch Simplastic Foley CathetersFeb 24, 2017
120 days to decisionK162989 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Oct 27, 2016
Decision date	Feb 24, 2017
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflexmedical, Inc.
Location	Jeffrey, NH, US
Contact	LORI PFOHL
510(k) history	64 submissions · 61 cleared · 1985-2024

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