FDA 510(k) Premarket Notification

K161770 Rusch Silicone Foley Catheter

CLEARED

May 5, 2017
311 days to decision

K161770 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k161770/

SUBMISSION DETAILS

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

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