

K172807 Silicone Foley Catheter for single useJun 4, 2018
259 days to decisionK172807 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k172807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 18, 2017
Decision date	Jun 4, 2018
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Rongxin Medicine Minimal Invasion Technology
Location	Jintan City, CN
Contact	Ping Liu
510(k) history	1 submissions · 1 cleared · 2018-2018

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