

K181616 PSM 3-Way Silicone Foley CatheterSep 21, 2018
94 days to decisionK181616 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jun 19, 2018
Decision date	Sep 21, 2018
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pathway, LLC
Location	Santee, CA, US
Contact	David Stroup
510(k) history	3 submissions · 3 cleared · 2016-2020

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