

K212151 FLUME catheterNov 3, 2021
117 days to decisionK212151 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k212151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 9, 2021
Decision date	Nov 3, 2021
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Flume Catheter Company, Ltd.
Location	Frensham, GB
Contact	Roger Holmes
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Paladin Medical, Inc.
Contact	Elaine Duncan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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