FDA 510(k) Premarket Notification

K231101 Flume Catheter

CLEARED

Jun 29, 2023
72 days to decision

K231101 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k231101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Apr 18, 2023
Decision date	Jun 29, 2023
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Flume Catheter Company, Ltd.**
Location	Farnham, GB
Contact	Roger Holmes
510(k) history	1 submissions · 1 cleared · 2023-2023

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