FDA 510(k) Premarket Notification

K233411 Folysil Silicone Catheter

CLEARED

Apr 15, 2024
192 days to decision

K233411 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233411/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Oct 6, 2023
Decision date	Apr 15, 2024
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast Corp.**
Location	Marietta, GA, US
Contact	Brian Schmidt
510(k) history	54 submissions · 47 cleared · 1985-2025

REGULATORY CONSULTANT

Consulting firm	**Kompass Regulatory Consulting**
Contact	Kristen Swanson

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