FDA 510(k) Premarket Notification

K251116 Luja Coudé

CLEARED

Jun 27, 2025
77 days to decision

K251116 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k251116/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Apr 11, 2025
Decision date	Jun 27, 2025
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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