

K251116 Luja CoudéJun 27, 2025
77 days to decisionK251116 · Product code: **EZD** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251116/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026