

K250270 Luja SetApr 17, 2025
77 days to decisionK250270 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250270/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Straight (EZD)
Date received	Jan 30, 2025
Decision date	Apr 17, 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	Vallabha Tantry
510(k) history	54 submissions · 47 cleared · 1985-2025

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