

K241210 Luja CoudeNov 21, 2024
205 days to decisionK241210 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k241210/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Apr 30, 2024
Decision date	Nov 21, 2024
Days to decision	205 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

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