FDA 510(k) Premarket Notification

K233101 Luja Coude (20108 Male CH18 - large packaging)

CLEARED

Oct 26, 2023
30 days to decision

K233101 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Straight (EZD)
Date received	Sep 26, 2023
Decision date	Oct 26, 2023
Days to decision	30 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