CLEARED

Aug 25, 2023
217 days to decision

K230165 Luja Coudé (20118 Male CH8 - small packaging (Pocket size)), Luja Coudé (20111 Male CH10 - small packaging (Pocket size)), Luja Coudé (20112 Male CH12 - small packaging (Pocket size)), Luja Coudé (20114 Male CH14 - small packaging (Pocket size)), Luja Coudé (20101 Male CH10 - large packaging), Luja Coudé (20102 Male CH12 - large packaging), Luja Coudé (20104 Male CH14 - large packaging), Luja Coudé (20106 Male CH16 - large packaging)

K230165 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Jan 20, 2023
Decision date	Aug 25, 2023
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast**
Location	Plymouth, MN, US
Contact	Troy Thome
Website	http://www.coloplast.com/
510(k) history	15 submissions · 14 cleared · 2018-2024