FDA 510(k) Premarket Notification

K241028 Luja female (20051)

CLEARED

Jul 26, 2024
102 days to decision

K241028 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241028/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Apr 15, 2024
Decision date	Jul 26, 2024
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Luja female (20052); Luja female (20054); Luja female (20056)

APPLICANT

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