FDA 510(k) Premarket Notification

K221401 Self-Cath and Self-Cath Plus

CLEARED

Dec 2, 2022
200 days to decision

K221401 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221401/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	May 16, 2022
Decision date	Dec 2, 2022
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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