FDA 510(k) Premarket Notification

K222059 SpeediCath Flex Set

CLEARED

Sep 21, 2022
70 days to decision

K222059 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k222059/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Jul 13, 2022
Decision date	Sep 21, 2022
Days to decision	70 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