FDA 510(k) Premarket Notification

K973070 CONVEEN EASICATH SET

CLEARED

Nov 6, 1997
80 days to decision

K973070 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k973070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Aug 18, 1997
Decision date	Nov 6, 1997
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast Corp.**
Location	Marietta, GA, US
Contact	SYDNEY LILLY
510(k) history	54 submissions · 47 cleared · 1985-2025