FDA 510(k) Premarket Notification

K182122 Ureteric Catheters

CLEARED

Oct 4, 2018
59 days to decision

K182122 · Product code: **EYB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k182122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ureteral, Gastro-urology (EYB)
Date received	Aug 6, 2018
Decision date	Oct 4, 2018
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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