FDA 510(k) Premarket Notification

K170531 Ureteral Dilators and Percutaneous Nephrostomy Dilators

CLEARED

Aug 17, 2017
176 days to decision

K170531 · Product code: **EZN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k170531/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Feb 22, 2017
Decision date	Aug 17, 2017
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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