

K170531 Ureteral Dilators and Percutaneous Nephrostomy DilatorsAug 17, 2017
176 days to decisionK170531 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170531/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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