

K172588 Balloon Catheter and Balloon Ureteral Dilator SetApr 19, 2018
233 days to decisionK172588 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k172588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Aug 29, 2017
Decision date	Apr 19, 2018
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Carly Powell
510(k) history	175 submissions · 153 cleared · 2006-2024

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