

**K173654 Ureteral Dilator Sets, Ureteral Dilators**Jul 17, 2018  
231 days to decisionK173654 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k173654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Nov 28, 2017
Decision date	Jul 17, 2018
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Kotei Aoki
510(k) history	175 submissions · 153 cleared · 2006-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173654/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026