

**K905375 ACCENT DG BALLOON URETERAL DILATOR SET**Apr 12, 1991  
133 days to decisionK905375 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k905375/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Nov 30, 1990
Decision date	Apr 12, 1991
Days to decision	133 days
Third-party review	No

**APPLICANT**

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Company	<b>Cook Urological, Inc.</b>
Location	Spencer, IN, US
Contact	MICHELLE YOUNG
510(k) history	104 submissions · 102 cleared · 1986-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905375/>; 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 June 19, 2026