

**K915392 ACCENT DG BALLOON URTERAL DILATOR SET,  
10CM**Mar 18, 1992  
110 days to decisionK915392 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k915392/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Nov 29, 1991
Decision date	Mar 18, 1992
Days to decision	110 days
Third-party review	No
Summary / Statement	Statement

**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/k915392/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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