

**K921839 ENTRAC URETERAL BALLOON DILATION  
CATHETERS**Oct 28, 1992  
194 days to decisionK921839 · Product code: **EZN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k921839/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Apr 17, 1992
Decision date	Oct 28, 1992
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Medical Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	SUSAN TESMER
510(k) history	72 submissions · 72 cleared · 1979-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921839/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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