

**K942578 ENTRAC URETERAL BALLOON DILATATION
CATHETERS**Aug 19, 1994
80 days to decisionK942578 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k942578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	May 31, 1994
Decision date	Aug 19, 1994
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Systems, Inc.
Location	Mchenry, IL, US
Contact	SYLVIA L GUBBE
510(k) history	72 submissions · 72 cleared · 1979-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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