

K940542 NAMIC ARIA(TM) INFLATION DEVICEApr 18, 1994
70 days to decisionK940542 · Product code: **EZN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k940542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Feb 7, 1994
Decision date	Apr 18, 1994
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k940542/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026