

**K920711 ENTRAC URETHRAL BALLOON DILATATION
CATHETER**May 6, 1992
78 days to decisionK920711 · Product code: **KOE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k920711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral (KOE)
Date received	Feb 18, 1992
Decision date	May 6, 1992
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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