

K920551 120 FR OPTILUME PROSTATE BALLOON DILATOROct 28, 1992
265 days to decisionK920551 · Product code: **KOE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k920551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral (KOE)
Date received	Feb 6, 1992
Decision date	Oct 28, 1992
Days to decision	265 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k920551/> 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