

**K912935 AMS MALLEABLE 600 AND 600M PENILE
PROSTHESIS**Mar 18, 1992
257 days to decisionK912935 · Product code: **F AE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k912935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Jul 5, 1991
Decision date	Mar 18, 1992
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912935/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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