

**K831660 AMS MALLEABLE PENILE PROSTHESIS**Aug 8, 1983  
77 days to decisionK831660 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k831660/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	May 23, 1983
Decision date	Aug 8, 1983
Days to decision	77 days
Third-party review	No

**APPLICANT**

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Company	<b>American Medical Systems, Inc.</b>
Location	Mchenry, IL, US
510(k) history	72 submissions · 72 cleared · 1979-2013

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k831660/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026