

**K821627 THE ARTIFICIAL URINARY SPHINCTER**Aug 10, 1982  
69 days to decisionK821627 · Product code: **FAG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k821627/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Urethral Sphincter (FAG)
Date received	Jun 2, 1982
Decision date	Aug 10, 1982
Days to decision	69 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/k821627/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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