

K090663 AMS SPECTRA CONCEALABLE PENILE PROSTHESISApr 9, 2009
28 days to decisionK090663 · Product code: **FAE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k090663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Penile (FAE)
Date received	Mar 12, 2009
Decision date	Apr 9, 2009
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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