

K821628 THE INFLATABLE PENILE PROSTHESISAug 10, 1982
69 days to decisionK821628 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k821628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Jun 2, 1982
Decision date	Aug 10, 1982
Days to decision	69 days
Third-party review	No

APPLICANT

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

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