

K830048 INFLATABLE PENILE PROSTH. - CYLINDERApr 12, 1983
92 days to decisionK830048 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k830048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Jan 10, 1983
Decision date	Apr 12, 1983
Days to decision	92 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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Device record: <https://www.510kdatabase.net/k830048/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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