

K901482 700 ULTREX PENILE PROSTHESIS 12MM DIAMETERJun 27, 1990
90 days to decisionK901482 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k901482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Mar 29, 1990
Decision date	Jun 27, 1990
Days to decision	90 days
Third-party review	No

APPLICANT

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

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