

K951716 AMS 650 MALLERABLE PENIEL PROSTHESISJul 6, 1995
83 days to decisionK951716 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k951716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Apr 14, 1995
Decision date	Jul 6, 1995
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

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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