

K963328 AMS AMBICOR PENILE PROSTHESISDec 4, 1996
103 days to decisionK963328 · Product code: **FAE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k963328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Aug 23, 1996
Decision date	Dec 4, 1996
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026