

**K910214 AMS 700 ULTREX(TM) PRECONNECTED PENILE PROSTHESIS**Apr 25, 1991  
98 days to decisionK910214 · Product code: **FAE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k910214/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Jan 17, 1991
Decision date	Apr 25, 1991
Days to decision	98 days
Third-party review	No

**APPLICANT**

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Company	<b>American Medical Corp.</b>
Location	Minnetonka, MN, US
Contact	QUINLAN SMITH
510(k) history	3 submissions · 3 cleared · 1991-1992

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910214/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026