

**K912344 MODIFIED DURAPHASE(TM) IMPLANTED PENILE PROSTHESIS**Oct 11, 1991  
136 days to decisionK912344 · Product code: **FAE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k912344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	May 28, 1991
Decision date	Oct 11, 1991
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dacomed Corp.</b>
Location	Mchenry, IL, US
Contact	MARY M.WILEN
510(k) history	20 submissions · 20 cleared · 1981-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912344/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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