

**K971576 REJOYN PENILE SUPPORT SYSTEM**Oct 16, 1997  
174 days to decisionK971576 · Product code: **LKY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k971576/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Apr 25, 1997
Decision date	Oct 16, 1997
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Medtech</b>
Location	Washington, DC, US
Contact	DONALD R STONE
510(k) history	1 submissions · 1 cleared · 1997-1997

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