

**K971443 RAPPORT V.T.D.**Sep 26, 1997  
158 days to decisionK971443 · Product code: **LKY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k971443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Apr 21, 1997
Decision date	Sep 26, 1997
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Owen Mumford USA, Inc.</b>
Location	Marietta, GA, US
Contact	ROBERT E SHAW
510(k) history	10 submissions · 10 cleared · 1995-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971443/> 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 29, 2026