

**K974196 MEGAVAC SYSTEM**May 12, 1998  
186 days to decisionK974196 · Product code: **LKY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k974196/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Nov 7, 1997
Decision date	May 12, 1998
Days to decision	186 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Barry J. Kaplan, Inc.</b>
Location	San Diego, CA, US
Contact	BARRY J KAPLAN
510(k) history	1 submissions · 1 cleared · 1998-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974196/> 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 July 1, 2026