

**K980291 IMPOWER EXTERNAL VACUUM SYSTEM**Mar 11, 1998  
44 days to decisionK980291 · Product code: **LKY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k980291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Jan 26, 1998
Decision date	Mar 11, 1998
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imagyn Medical Technologies, Inc.</b>
Location	Richland, MI, US
Contact	RONALD H BERGESON
510(k) history	7 submissions · 6 cleared · 1998-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980291/> 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 May 19, 2026