

**K000124 SENSATION -VACUUM ASSIST DEVICES**Jul 10, 2000  
174 days to decisionK000124 · Product code: **LKY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k000124/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Jan 18, 2000
Decision date	Jul 10, 2000
Days to decision	174 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Prosurg, Inc.</b>
Location	San Jose, CA, US
Contact	LEE BUI
510(k) history	16 submissions · 16 cleared · 2000-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000124/> 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 17, 2026