

**K955856 TEX-AID BLUE**Feb 16, 1996  
52 days to decisionK955856 · Product code: **LKY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k955856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Dec 26, 1995
Decision date	Feb 16, 1996
Days to decision	52 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Laborie Medical Technologies, Ltd.</b>
Location	North Attleboro, MA, US
Contact	FRED BUFFA
510(k) history	11 submissions · 11 cleared · 1992-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955856/> 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 22, 2026