

**K942563 ELITE BIOFEEDBACK**Jun 6, 1995  
371 days to decisionK942563 · Product code: **HIR** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k942563/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	May 31, 1994
Decision date	Jun 6, 1995
Days to decision	371 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/k942563/> 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