

**K162689 Vibrance Pelvic Trainer**Jun 8, 2017  
254 days to decisionK162689 · Product code: **HIR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k162689/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Sep 27, 2016
Decision date	Jun 8, 2017
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioinfinity (M) Sdn. Bhd.</b>
Location	Austin, TX, US
Contact	NG SHEA KANG
510(k) history	2 submissions · 2 cleared · 2014-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162689/> 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 1, 2026