

K160758 PeriCoach OTCJul 11, 2016
115 days to decisionK160758 · Product code: **HIR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Mar 18, 2016
Decision date	Jul 11, 2016
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Analytica, Ltd.
Location	Brisbane, AU
Contact	GEOFF DALY
510(k) history	2 submissions · 2 cleared · 2015-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160758/> Data sourced from FDA 510(k) public records (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. - Generated June 2, 2026