

K140780 KEGEL SMART, KEGELSMART PEARLSep 10, 2014
166 days to decisionK140780 · Product code: **HIR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k140780/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Mar 28, 2014
Decision date	Sep 10, 2014
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Regulatory Insight, Inc.
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	4 submissions · 4 cleared · 2002-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140780/> 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 May 26, 2026