FDA 510(k) Premarket Notification

K140780 KEGEL SMART, KEGELSMART PEARL

CLEARED

Sep 10, 2014
166 days to decision

K140780 · 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