FDA 510(k) Premarket Notification

K141893 VIBRANCE KEGEL DEVICE (VKD)

CLEARED

Dec 18, 2014
157 days to decision

K141893 · Product code: **HIR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k141893/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Jul 14, 2014
Decision date	Dec 18, 2014
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bioinfinity (M) Sdn. Bhd.**
Location	Austin, TX, US
Contact	Carrie Hetrick
510(k) history	2 submissions · 2 cleared · 2014-2017