

K193364 Intimate Rose Kegel Exercise SystemAug 24, 2020
264 days to decisionK193364 · Product code: **HIR** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k193364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Dec 4, 2019
Decision date	Aug 24, 2020
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Plus EV Holdings DbA Intimate Rose
Location	North Kansas City, MO, US
Contact	Aaron Wilt
510(k) history	3 submissions · 3 cleared · 2020-2024

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