

**K241748 Intimate Rose Vaginal Dilators**Aug 14, 2024  
57 days to decisionK241748 · Product code: **HDX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k241748/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	Jun 18, 2024
Decision date	Aug 14, 2024
Days to decision	57 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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