

K231430 Intimate Rose Vaginal DilatorsJun 7, 2023
21 days to decisionK231430 · Product code: **HDX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k231430/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	May 17, 2023
Decision date	Jun 7, 2023
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
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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