FDA 510(k) Premarket Notification

K231430 Intimate Rose Vaginal Dilators

CLEARED

Jun 7, 2023
21 days to decision

K231430 · Product code: **HDX** · Obstetrics & Gynecology
Source: 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 Dba 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