FDA 510(k) Premarket Notification

K222492 Hope&Her Vaginal Dilators

CLEARED

Jun 27, 2023
314 days to decision

K222492 · Product code: **HDX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k222492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	Aug 17, 2022
Decision date	Jun 27, 2023
Days to decision	314 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lujena, Inc.**
Location	El Cajon, CA, US
Contact	Troy Gemmer
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Matrix Medical Consulting, Inc.**
Contact	Alan Donald

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