

K222492 Hope&Her Vaginal DilatorsJun 27, 2023
314 days to decisionK222492 · Product code: **HDX** · Obstetrics & GynecologySource: <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](https://accessdata.fda.gov)

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