

K233689 Hope&Her Vaginal DilatorsMay 2, 2024
167 days to decisionK233689 · Product code: **HDX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k233689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	Nov 17, 2023
Decision date	May 2, 2024
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233689/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026