FDA 510(k) Premarket Notification

K233689 Hope&Her Vaginal Dilators

CLEARED

May 2, 2024
167 days to decision

K233689 · 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