FDA 510(k) Premarket Notification

K230518 HydraDose Vaginal Suppositories

CLEARED

Jun 23, 2023
116 days to decision

K230518 · Product code: **NUC** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k230518/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Feb 27, 2023
Decision date	Jun 23, 2023
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**MD Labs, LLC**
Location	Westlake Village, CA, US
Contact	Harout Achekian
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Med-Device Consulting, Inc.**
Contact	Louie Goryoka

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