

K230518 HydraDose Vaginal SuppositoriesJun 23, 2023
116 days to decisionK230518 · Product code: **NUC** · Obstetrics & GynecologySource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230518/> 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 27, 2026