

K212000 MedleyNov 18, 2021
143 days to decisionK212000 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jun 28, 2021
Decision date	Nov 18, 2021
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Good Clean Love, Inc.
Location	Eugene, OR, US
Contact	Wendy Strgar
510(k) history	7 submissions · 7 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	Amin Talati Wasserman, Llp
Contact	Abhishek Gurnani

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/k212000/> 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 26, 2026