

K250488 Cerynë Intimate CareDec 12, 2025
296 days to decisionK250488 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Feb 19, 2025
Decision date	Dec 12, 2025
Days to decision	296 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ansella Therapeutics
Location	Cypress, TX, US
Contact	Maria Carrasco
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250488/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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