

K200239 Astroglide Organix GelNov 13, 2020
287 days to decisionK200239 · Product code: **NUC** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k200239/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jan 31, 2020
Decision date	Nov 13, 2020
Days to decision	287 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofilm, Inc.
Location	Vista, CA, US
Contact	Richard Hines
510(k) history	17 submissions · 17 cleared · 1994-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200239/> 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