

K220653 Astroglide Glycerin & Paraben FreeMay 6, 2022
60 days to decisionK220653 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k220653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Mar 7, 2022
Decision date	May 6, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220653/> 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