

**K163395 Astroglide Diamond Silicone Gel Personal Lubricant**Feb 10, 2017  
67 days to decisionK163395 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k163395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Dec 5, 2016
Decision date	Feb 10, 2017
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163395/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026