

**K254101 Julva Velvé Water-Based Personal Lubricant**Apr 16, 2026  
118 days to decisionK254101 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k254101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Dec 19, 2025
Decision date	Apr 16, 2026
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Golden Isles Medical, Inc.</b>
Location	Brunswick, GA, US
Contact	Louie Goryoka
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Med-Device Consulting, Inc.</b>
Contact	Louie Goryoka

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254101/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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